
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM S-1
REGISTRATION STATEMENT**

*Under
The Securities Act of 1933*

BICARA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)
116 Huntington Avenue, Suite 703
Boston, MA 02116
617-468-4219

85-2903745
(I.R.S. Employer
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED _____, 2024
PRELIMINARY PROSPECTUS

Shares



Common Stock

This is the initial public offering of shares of common stock of Bicara Therapeutics Inc.

We are offering _____ shares of our common stock. Prior to this offering, there has been no public market for our common stock. We expect the initial public offering price to be between \$ _____ and \$ _____ per share. We intend to apply to list our common stock on The Nasdaq Global Market, or Nasdaq, under the symbol "BCAX."

We are an "emerging growth company" and "smaller reporting company" as defined under the U.S. federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings. See the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. Please see the section titled "[Risk Factors](#)" beginning on page 13 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

| | <u>Per share</u> | <u>Total</u> |
|---|------------------|--------------|
| Initial public offering price | \$ _____ | \$ _____ |
| Underwriting discounts and commissions ⁽¹⁾ | \$ _____ | \$ _____ |
| Proceeds, before expenses, to us | \$ _____ | \$ _____ |

(1) See the section titled "Underwriting" for additional information regarding underwriting compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional _____ shares of common stock at the initial offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock on or about _____, 2024.

Morgan Stanley

TD Cowen

Cantor

Stifel

Prospectus dated _____, 2024

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of and for the three months ended March 31, 2024 and 2023 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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Through and including _____, 2024 (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of the date on the front cover of this prospectus, regardless of its time delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

We own various U.S. federal trademark applications, registered and unregistered trademarks, and trade names including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

The estimates, statistical and market data and certain other information concerning our industry, market and competitive position used throughout this prospectus are based on our own internal estimates and research, independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do

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not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "*Risk Factors*" and elsewhere in this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, the terms “Bicara,” “the Company,” “we,” “us,” and “our” in this prospectus refer to Bicara Therapeutics Inc. and its wholly owned subsidiary, or either or both of them as the context may require.

Overview

We are a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Our lead program BCA101 is a bifunctional antibody that combines two clinically validated targets, an epidermal growth factor receptor, or EGFR, directed monoclonal antibody with a domain that binds to human transforming growth factor beta, or TGF- β . Through this dual-targeting mechanism, BCA101 has the potential to exert potent anti-tumor activity by simultaneously blocking both cancer cell-intrinsic EGFR survival and proliferation, as well as the immunosuppressive TGF- β signaling within the tumor microenvironment, or TME. BCA101 directs the TGF- β inhibitor into the immediate TME through the binding of EGFR on tumor cells, which we believe will lead to durable responses and an increase in overall survival, or OS, while reducing the adverse effects typically associated with systemic TGF- β inhibition. BCA101 is initially being developed in head and neck squamous cell carcinoma, or HNSCC, where there remains a significant unmet need. We intend to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in recurrent/metastatic, or R/M, HNSCC excluding patients associated with human papillomavirus infection, or HPV-positive patients, with oropharyngeal squamous cell carcinoma, or OPSCC, in . Based on discussions with the U.S. Food and Drug Administration, or FDA, we believe that this trial may enable us to seek accelerated approval for BCA101 in combination with pembrolizumab.

We are conducting an ongoing Phase 1/1b trial of BCA101, which includes a cohort of HNSCC patients who were treatment-naïve in the R/M setting. In this cohort, treatment with BCA101 in combination with pembrolizumab resulted in a 54% (21/39) overall response rate, or ORR, in the efficacy evaluable population, and a 64% (18/28) ORR in patients not associated with human papillomavirus infection, or HPV-negative patients. These data reflect a substantial increase over the 19% historical response rate observed in a Phase 3 trial with pembrolizumab monotherapy, the current standard of care in R/M HNSCC. Furthermore, the combination therapy demonstrated an 18% (5/28) complete response rate, or CR rate, and a median progression-free survival, or mPFS, of 9.8 months in HPV-negative patients. With at least 12 months of follow-up, median OS has not yet been reached, and we expect to announce updated interim Phase 1/1b data at future medical meetings. Based on the clinical data generated to date, we believe that BCA101 in combination with pembrolizumab has the potential to become a first-line chemotherapy-free standard of care therapy in HPV-negative R/M HNSCC.

We also believe BCA101 has the potential to provide meaningful clinical benefit in other solid tumors where there is a strong biologic rationale for the dual inhibition of both EGFR and TGF- β , such as colorectal cancer and other squamous cell carcinomas which typically overexpress EGFR and TGF- β pathways. We have demonstrated preliminary activity of BCA101 in combination with pembrolizumab or as a monotherapy across several squamous cell carcinomas, including cutaneous squamous cell carcinoma, or CSCC. Within our Phase 1/1b dose expansion cohorts, we have observed to date a preliminary 42% (5/12) ORR with BCA101 monotherapy in relapsed and/or refractory CSCC patients.

We have built a platform designed to facilitate the development of bifunctional therapies that precisely target the tumor and deliver a tumor-modulating payload to the tumor site. This dual-targeting approach both

enhances drug exposure within the TME and limits systemic toxicity. This approach was deployed in the development of BCA101, where we believe the bifunctional design can improve upon the therapeutic profile of immunotherapies and targeted therapies by addressing resistance mechanisms and limiting off-target toxicity, therefore, enhancing the treatment effect and tolerability for targeted patient populations with cancer.

HNSCC Background

HNSCC is one of the most common cancers in the United States and globally with a rising incidence anticipated to reach one million new global cases annually by 2030. Ten percent of HNSCC patients are diagnosed with metastatic disease and up to 30% develop a recurrence or metastases over time after initial treatment for advanced HNSCC. Median OS for patients with R/M HNSCC is only 12 months. Most cases of HNSCC are believed to arise from mutations that accumulate due to carcinogenic exposure, such as tobacco smoke, or by HPV. Approximately 80% of patients with R/M HNSCC are HPV-negative, a status associated with a worse prognosis. Pembrolizumab monotherapy is the standard of care for R/M HNSCC patients who have evidence of PD-L1 expressing tumors is pembrolizumab monotherapy. The KEYNOTE-048 Phase 3 trial of pembrolizumab conducted by Merck & Co. Inc., or Merck & Co, demonstrated an ORR of 19% with a mPFS of 3.2 months in a population of HPV-negative and HPV-positive patients with combined positive scores, or CPS, greater than or equal to one. For patients with a CPS less than one and no PD-L1 expression within their TME, the typical standard of care is the EXTREME regimen, a combination of cetuximab and chemotherapy, which has low response rates and survival, as well as a difficult tolerability profile.

We believe the poor prognoses in HPV-negative R/M HNSCC and the low ORR associated with available therapies may be attributed to the elevated levels of TGF- β observed in these patients. It has been shown in translational studies that EGFR inhibition leads to further increases in TGF- β levels which result in the development of resistance to EGFR-targeted therapeutics. We believe blocking TGF- β has the potential to prevent resistance and improve the anti-tumor activity of anti-EGFR therapies, leading to more durable responses and an increase in OS. Similarly, inhibiting TGF- β may reduce the fibrosis and immune-exclusion within the TME that could be responsible for the low efficacy seen with checkpoint inhibitors in these immunosuppressive, or “cold” tumors. We believe promoting immune activation via TGF- β blockade may translate to significant increases in anti-tumor efficacy, particularly in the depth and durability of responses in combination with anti-PD1 therapies.

Our Dual-Targeting Mechanism: EGFR and TGF- β

EGFR is the primary member of a larger family of cell-surface growth factor receptors harboring intrinsic tyrosine kinase function. EGFR is involved in many tumor-promoting pathways. Its overexpression has been linked to multiple squamous cell cancers, including HNSCC, where EGFR expression has been shown to be greater than 90%. EGFR has been a long-standing focus for cancer drug development due to the correlation between EGFR expression, poor prognosis and resistance to therapy. Cetuximab is an EGFR-directed monoclonal antibody approved for HNSCC and colorectal cancer that drives anti-tumor responses by inhibiting EGFR signaling and through antibody-dependent cell-mediated cytotoxicity, or ADCC. However, acquired resistance mechanisms to cetuximab can prevent durable responses. We believe that there is a significant market opportunity for EGFR targeted therapies with improved efficacy, durability and OS compared to cetuximab.

TGF- β is a cytokine that controls a range of biological functions and is widely understood to play a critical role in cancer. TGF- β perpetuates tumor survival by promoting tumor cell proliferation, migration, invasion and metastasis. TGF- β also serves as an immunosuppressant, inhibiting both natural killer, or NK, cells and cytotoxic T cells. The inhibition of TGF- β has been demonstrated to improve anti-tumor responses *in vivo*. However, these findings have not been translated into substantial improvements in clinical efficacy, which we believe may be due to the inability to sufficiently inhibit TGF- β directly within the TME. Increased TGF- β expression within the TME contributes to an immune-excluded environment.

BCA101 was designed to leverage the well-established biologies of both the clinically validated anti-EGFR antibody cetuximab and a TGF- β binding domain to deliver a potent anti-tumor therapy, sequestering TGF- β directly to EGFR-expressing tumors with the goal of limiting off-target toxicity. We have shown both *in vitro* and *in vivo* that BCA101 performs as expected, by binding to both targets, localizing to the tumor, inhibiting tumor growth and suppressing TGF- β levels within tumors.

BCA101 was designed to overcome key shortcomings of prior approaches to targeting EGFR and TGF- β .

Specifically, we believe that BCA101 is differentiated from previous and existing approaches given the following:

- **BCA101 localizes TGF- β inhibition directly to EGFR expressing tumor cells.** We believe this will lead to higher concentrations within the TME to increase the inhibition, reduce overall dose and enhance tolerability.
- **BCA101 may help prevent acquired resistance to EGFR-targeted therapies.** Dual targeting of TGF- β alongside EGFR may prevent key resistance mechanisms driven by upregulation of TGF- β and may drive durable tumor responses.
- **BCA101 synergizes with anti-PD-1 therapies.** Targeting TGF- β directly in the TME may relieve immune cell suppression and exclusion and enhance both the immune response as well as the activity of anti-PD-1 therapies.

BCA101 Clinical results

We are conducting an ongoing Phase 1/1b trial in patients with EGFR-driven solid tumors. This trial has the goal of establishing safety and tolerability, as well as the recommended dose for expansion for both BCA101 monotherapy and BCA101 in combination with pembrolizumab across various tumor types. Data from our Phase 1/1b dose expansion cohort evaluating 1500mg of BCA101 in combination with pembrolizumab in efficacy-evaluable first-line R/M HNSCC patients with a CPS greater than or equal to one was first presented in an oral presentation at an American Society of Clinical Oncology meeting in June 2023. We demonstrated a meaningful 54% (21/39) ORR across both HPV-negative and HPV-positive R/M HNSCC, a notable increase compared to historical published data for pembrolizumab monotherapy. We also observed a markedly higher ORR of 64% (18/28) in the HPV-negative subset. This is consistent with the HPV-negative subset having elevated levels of EGFR and TGF- β , where we believe BCA101 has potential to achieve differentiated clinical outcomes.

As depicted in the Figure below, in the HPV-negative subset, response rates of more than 50% were observed in both the CPS 1 through 19 and CPS greater than or equal to 20 subgroups. This is notable as pembrolizumab is known to have a lower efficacy in the CPS 1-19 subset. We also observed that 18% (5/28) of HPV-negative patients achieved a CR and several other patients achieved deep partial responses, including 5 other patients with responses greater than 80%. The CR rate we observed in this cohort appears to be significantly higher compared to those previously reported in investigator-sponsored trials, or ISTs, of cetuximab in combination with pembrolizumab or nivolumab, as well as the KEYNOTE-048 study with pembrolizumab, of approximately 3%.

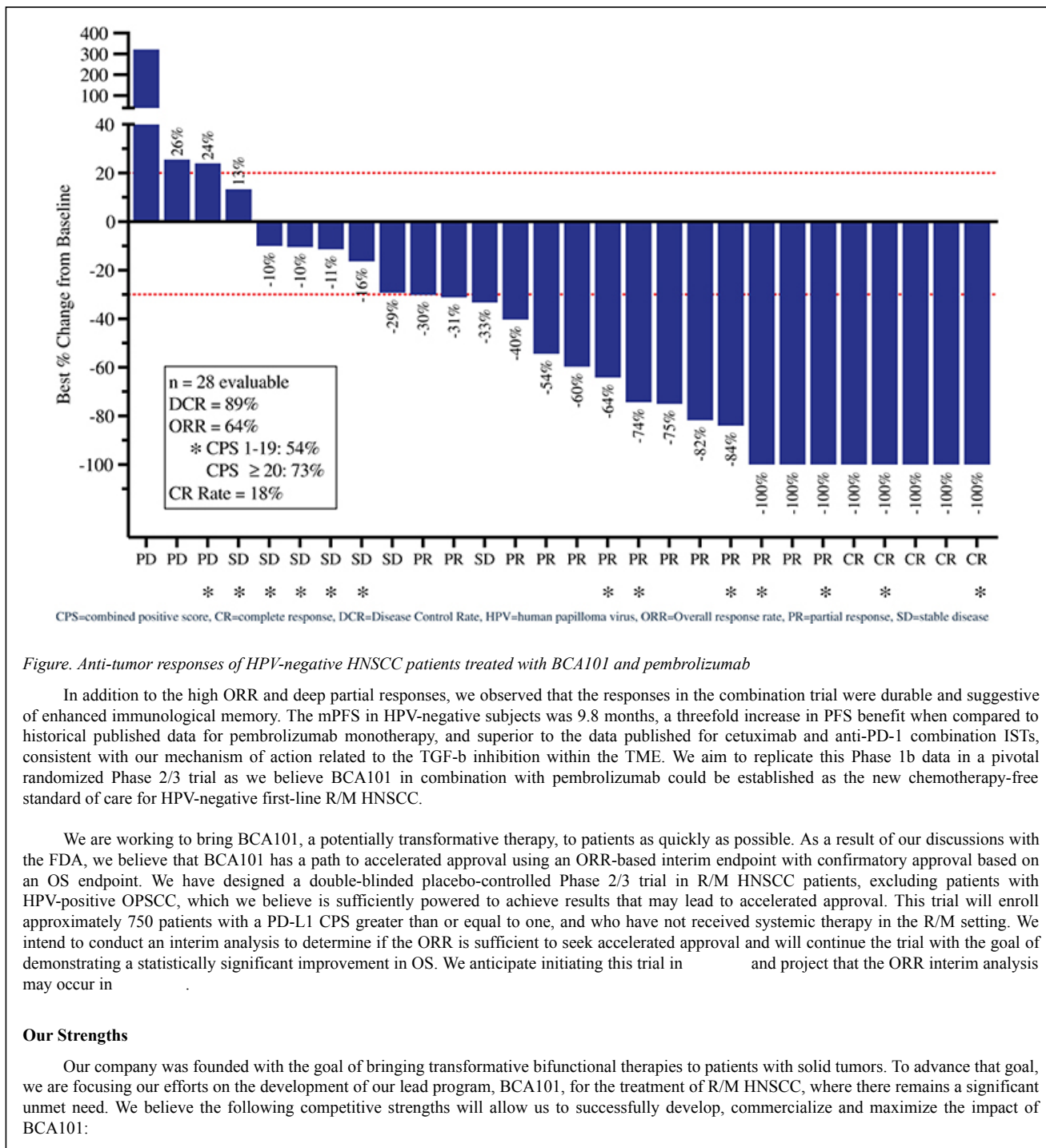


Figure. Anti-tumor responses of HPV-negative HNSCC patients treated with BCA101 and pembrolizumab

In addition to the high ORR and deep partial responses, we observed that the responses in the combination trial were durable and suggestive of enhanced immunological memory. The mPFS in HPV-negative subjects was 9.8 months, a threefold increase in PFS benefit when compared to historical published data for pembrolizumab monotherapy, and superior to the data published for cetuximab and anti-PD-1 combination ISTs, consistent with our mechanism of action related to the TGF- β inhibition within the TME. We aim to replicate this Phase 1b data in a pivotal randomized Phase 2/3 trial as we believe BCA101 in combination with pembrolizumab could be established as the new chemotherapy-free standard of care for HPV-negative first-line R/M HNSCC.

We are working to bring BCA101, a potentially transformative therapy, to patients as quickly as possible. As a result of our discussions with the FDA, we believe that BCA101 has a path to accelerated approval using an ORR-based interim endpoint with confirmatory approval based on an OS endpoint. We have designed a double-blinded placebo-controlled Phase 2/3 trial in R/M HNSCC patients, excluding patients with HPV-positive OPSCC, which we believe is sufficiently powered to achieve results that may lead to accelerated approval. This trial will enroll approximately 750 patients with a PD-L1 CPS greater than or equal to one, and who have not received systemic therapy in the R/M setting. We intend to conduct an interim analysis to determine if the ORR is sufficient to seek accelerated approval and will continue the trial with the goal of demonstrating a statistically significant improvement in OS. We anticipate initiating this trial in [redacted] and project that the ORR interim analysis may occur in [redacted].

Our Strengths

Our company was founded with the goal of bringing transformative bifunctional therapies to patients with solid tumors. To advance that goal, we are focusing our efforts on the development of our lead program, BCA101, for the treatment of R/M HNSCC, where there remains a significant unmet need. We believe the following competitive strengths will allow us to successfully develop, commercialize and maximize the impact of BCA101:

- **Validated dual-targeting mechanism of action with potential to exert potent and durable anti-tumor activity.**

BCA101 is a bifunctional antibody designed to simultaneously block both cancer cell-intrinsic EGFR survival and proliferation, as well as the well-understood immunosuppressive TGF- β signaling within the TME. BCA101 leverages the established biology of the clinically validated anti-EGFR antibody cetuximab. However, BCA101 is differentiated from existing therapies through the targeting of TGF- β , which localizes the ligand to EGFR expressing tumor cells, potentially increasing its activity at the tumor site and limiting systemic toxicity. Importantly, TGF- β inhibition synergizes with EGFR, which we believe will prevent resistance to treatment and lead to more durable responses.

- **Clinical data generated to date representing meaningful improvements over standard of care.**

We have generated compelling interim clinical data for BCA101 in a Phase 1/1b trial of R/M HNSCC patients. In this trial, treatment with BCA101 in combination with pembrolizumab led to a 64% (18/28) ORR in HPV-negative patients, which is a substantial increase over the 19% historical response rate reported with pembrolizumab monotherapy in R/M HNSCC in the KEYNOTE-048 Phase 3 trial conducted by Merck & Co that included HPV-negative and HPV-positive patients. The combination also demonstrated an 18% (5/28) CR rate and mPFS to 9.8 months in the same patient population. With at least 12 months of follow-up, median OS has not yet been reached, and we expect to announce updated interim Phase 1/1b data at future medical meetings. We believe these encouraging initial clinical data demonstrate the potential of BCA101, administered in combination with pembrolizumab, to become a chemotherapy-free, first-line therapy for HPV-negative R/M HNSCC patients.

- **Potential to address significant unmet need in HPV-negative R/M HNSCC with clear development pathway.**

HNSCC is one of the most common cancers, accounting for approximately 4% of all cancers in the United States. An estimated 80% of R/M HNSCC cases are HPV-negative, a status associated with significantly worse outcomes compared to HPV-positive patients. We are prioritizing our initial development efforts in HPV-negative R/M HNSCC given the significant unmet need for durable therapies in this patient population. We also believe that BCA101 will be most effective in this patient subset given the (1) high expression of EGFR, (2) elevated levels of TGF- β and (3) current preclinical and clinical data, including from our own Phase 1/1b study, supporting increased activity within HPV-negative patients. We believe our deliberate patient selection strategy provides the best opportunity to demonstrate the potential of BCA101 as a first-line therapy. We plan to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in HPV-negative R/M HNSCC in . Based on discussions with the FDA, we believe that this trial may enable an accelerated approval pathway for BCA101.

- **Potential to expand the clinical development of BCA101 in additional patient populations within HNSCC and other solid tumors of squamous cell origin.**

Beyond our initial development plans, we believe there are significant opportunities to expand the clinical development of BCA101 to other populations of HNSCC patients, including for the treatment of locally advanced HPV-negative HNSCC and in the neoadjuvant or adjuvant setting. We also believe BCA101 has the potential to provide meaningful clinical benefit in other EGFR-expressing solid tumors of squamous cell origin, such as colorectal cancer and other squamous cell carcinomas where there is a strong biologic rationale for the dual-inhibition of EGFR and TGF- β pathways. We plan to explore these additional development opportunities to maximize the potential of BCA101 for the treatment of cancer.

- **Strong and experienced team with deep expertise in clinical development.**

We have assembled a seasoned leadership team with extensive and highly relevant experience in the field of oncology drug development. Our organization is comprised of scientific, clinical and business

leaders with broad biotechnology expertise. We have a strong track record of study design and execution, exemplified by the rapid enrollment of our Phase 1/1b study. Our mission-driven team will continue to dedicate our collective efforts and resources to our shared goal of delivering transformative therapies to cancer patients.

Our Team

We have assembled a seasoned leadership team of scientific, clinical and business leaders with broad expertise in biotechnology. Claire Mazumdar, Ph.D., M.B.A., our Chief Executive Officer, was previously part of the founding team and led business development and corporate strategy at Rheos Medicines, Inc. Dr. Mazumdar served as a Senior Associate at Third Rock Ventures, LLC, where she focused on company formation and supported business development for their portfolio companies. Ryan Cohlhepp, Pharm.D., our President and Chief Operating Officer, was a founding executive at Rheos Medicines, Inc., and prior to that, was Vice President of Marketing, Operations and Analytics at Takeda Oncology where he was responsible for the company's commercial oncology portfolio in the United States. David Raben, M.D., our Chief Medical Officer, is currently a board-certified radiation oncologist with more than 25 years of biopharma and academic translational oncology experience. His prior roles include Vice President of Global Product Development and Product General Manager of Oncology at Amgen, Inc. and Vice President and Franchise Leader of Clinical Oncology at Genentech, Inc. focused on non-small cell lung cancer, or NSCLC, skin cancer and HNSCC. Ivan Hyep, our Chief Financial Officer, previously served as Head of Finance at MOMA Therapeutics and Director of Finance at Third Rock Ventures, LLC after 10 years at Bain Capital, LP. Lara Meisner, J.D., our Chief Legal Officer, previously served as Chief Legal Officer at Viridian Therapeutics, Inc. and in various senior legal roles at Astria Therapeutics, Inc. and Verastem, Inc.

Our team is supported by a group of investors who have shared our vision and commitment to developing transformative bifunctional therapies for patients with solid tumors. Since our inception, we have raised \$353 million, including a \$165 million Series C financing in December 2023. Our leading syndicate of investors includes RA Capital Management, Red Tree Venture Capital, F-Prime Capital, Eight Roads Ventures, Omega Funds, Invus and TPG, as well as Biocon Limited, a global biopharmaceutical company and leader in the development of biologics.

Summary of Material Risks Associated with our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- Even if this offering is successful, we will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business is highly dependent on the success of BCA101. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize BCA101, or if we experience delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize BCA101 and any future product candidates.
- BCA101 or any future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- The commercial success of BCA101 or any future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.
- Our ability to develop product candidates, leverage our potential and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Additionally, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “*Risk Factors*” and the other information set forth in this prospectus, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future, growth prospects.

Corporate History

We were incorporated under the laws of the State of Delaware on December 12, 2018 under the name “Bicara Therapeutics Inc.” Our principal corporate office is located at 116 Huntington Avenue, Suite 703, Boston, MA 02116, and our telephone number is 617-468-4219. We have one subsidiary, Bicara Securities Corporation, formed in October 2023 under the laws of the Commonwealth of Massachusetts. Our website address is www.bicara.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;

- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of these elections, the information that we provide in this prospectus including our financial statements, may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that (i) our voting and non-voting common stock held by non-affiliates is \$250 million or more, measured on the last business day of our second fiscal quarter, or (ii) our annual revenues are \$100 million or more, during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is \$700 million or more, measured on the last business day of our second fiscal quarter.

THE OFFERING

| | |
|--|---|
| Common stock offered | shares. |
| Underwriters' option to purchase additional shares | We have granted a 30-day option to the underwriters to purchase up to additional shares of common stock from us at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus. |
| Common stock to be outstanding immediately after this offering | shares (or shares if the underwriters exercise their option to purchase additional shares of common stock in full). |
| Use of proceeds | We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately \$ million, or \$ million if the underwriters exercise their option to purchase additional shares of common stock in full, assuming an initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for the following: (i) advance the development of BCA101 in head and neck squamous cell carcinoma, and fund our pivotal Phase 2/3 trial; (ii) fund expansion of BCA101 in additional head and neck squamous cell carcinoma patient populations; (iii) advance the development of BCA101 in additional solid tumors, such as colorectal cancer and other squamous cell carcinomas including the initiation of clinical trials, clinical research outsourcing and drug manufacturing; and (iv) the remainder for working capital and other general corporate purposes. See section titled "Use of Proceeds" on page 78 for additional information. |
| Risk factors | You should carefully read the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock. |
| Proposed Nasdaq Global Market symbol | BCAX |

The number of shares of our common stock to be outstanding after this offering is based on 313,533,421 shares of our common stock (which includes 436,290 shares of unvested restricted common stock and 192,600 shares of unvested early exercise stock options) outstanding as of December 31, 2023, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 306,985,117 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 44,837,663 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2023 under our 2019 Stock Option and Grant Plan, as amended, or 2019 Plan, at a weighted average exercise price of \$0.49 per share;
- 2,755,000 shares of common stock issuable upon the exercise of stock options granted after December 31, 2023 pursuant to our 2019 Plan, at a weighted average exercise price of \$0.68 per share;
- 4,239,537 shares of common stock reserved for future issuance as of December 31, 2023 under the 2019 Plan, which will cease to be available for issuance at the time that our 2024 Stock Option and Incentive Plan, or 2024 Plan, becomes effective;
- shares of common stock reserved for future issuance under our 2024 Employee Stock Purchase Plan, or ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; and
- shares of our common stock that will become available for future issuance under our 2024 Plan, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2024 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled, or withheld.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- the automatic conversion of all 306,985,117 outstanding shares of our redeemable convertible preferred stock into an aggregate of 306,985,117 shares of common stock immediately prior to the closing of this offering;
- no exercise of the outstanding options described above after December 31, 2023;
- no exercise by the underwriters of their option to purchase up to additional shares of common stock in this offering;
- a one-for- reverse stock split of our common stock, which will become effective prior to the completion of this offering; and
- the filing and effectiveness of our fifth amended and restated certificate of incorporation immediately prior to the closing of this offering and the effectiveness of our amended and restated bylaws upon the effectiveness of the registration statement of which this prospectus is a part.

SUMMARY FINANCIAL DATA

The following table sets forth our summary consolidated statements of operations for the years ended December 31, 2023 and 2022 and our summary consolidated balance sheet data as of December 31, 2023. The summary consolidated statements of operations data for the year ended December 31, 2023 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in any future periods, and our interim results are not necessarily indicative of the results that may be expected for the full year or any other period. You should read the following summary financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and the related notes included elsewhere in this prospectus.

| | Year ended December 31, | |
|---|-------------------------|--------------------|
| | 2023 | 2022 |
| (in thousands except shares and per share data) | | |
| Statement of Operations Data: | | |
| Operating expenses | | |
| Research and development - related party | \$ 9,244 | \$ 12,936 |
| Research and development | 21,373 | 18,376 |
| General and administrative | 9,272 | 6,344 |
| Total operating expenses | <u>39,889</u> | <u>37,656</u> |
| Loss from operations | (39,889) | (37,656) |
| Other (expenses) income | | |
| Interest expense - related party | — | (112) |
| Interest income | 1,314 | 4 |
| Change in fair value of Series B preferred stock tranche rights liability | (13,405) | — |
| Other expense, net | — | (80) |
| Total other expense | <u>(12,091)</u> | <u>(188)</u> |
| Net loss before income taxes | (51,980) | (37,844) |
| Income tax expense | (5) | (1) |
| Net loss | <u>\$ (51,985)</u> | <u>\$ (37,845)</u> |
| Net loss per share, basic and diluted | <u>\$ (9.69)</u> | <u>\$ (9.54)</u> |
| Weighted-average number of common shares outstanding, basic and diluted | 5,362,239 | 3,966,241 |
| Pro forma net loss per common share, basic and diluted | <u>\$ (0.36)</u> | |
| Pro forma weighted-average number of common shares outstanding, basic and diluted | <u>142,723,891</u> | |

| | As of December 31, 2023 | |
|--------------------------------------|---|--------------------------|
| | Actual | Pro forma ⁽¹⁾ |
| | Pro forma as adjusted ⁽²⁾ | |
| | (in thousands except shares and per share data) | |
| Balance Sheet Data: | | |
| Cash and cash equivalents | \$ 230,440 | \$230,440 |
| Working capital ⁽³⁾ | 215,988 | 215,988 |
| Total assets | 233,982 | 233,982 |
| Convertible preferred stock | 367,277 | — |
| Total stockholders' (deficit) equity | (148,769) | 218,508 |

(1) Gives effect to the automatic conversion of all 306,985,117 outstanding shares of our redeemable convertible preferred stock in the aggregate into the equivalent number of shares of our common stock immediately prior to the completion of this offering, and the filing and effectiveness of our fifth amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of _____ shares of our common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Pro forma as adjusted balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, assuming no change in the assumed initial public offering price per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our common stock. The risks described below are not the only ones facing us. The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment.

This prospectus also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in December 2018, and our operations to date have been limited to pre-commercial activities. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled \$52.0 million and \$37.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we have not yet generated revenues. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, BCA101.

We anticipate that our expenses will increase substantially if, and as, we:

- advance BCA101 through clinical development;
- seek regulatory approvals for BCA101 and any future our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of BCA101 and any future product candidate;

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- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- advancing any future product candidates into clinical development; seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- make any payments due under our license agreements and any potential milestones, royalties or other payments due under any future in-license or collaboration agreements; and
- make milestone, royalty, interest or other payments due under any future financing or other arrangements with third parties.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, Health Canada, the European Medicines Agency, or the EMA, or other comparable regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidate.

Even if this offering is successful, we will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, BCA101. Even if BCA101 or any future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations principally through private financings. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development of BCA101, continue to develop and deploy our bifunctional approach, commence additional preclinical studies and clinical trials, and continue to identify and develop additional product candidates either through internal development or through acquisitions or in-licensing product candidates.

As of December 31, 2023, we had \$230.4 million of cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents, together with the estimated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. In addition, based upon our current operating plan, we believe that the net proceeds

from this offering together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop BCA101. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for BCA101 or any future product candidates;
- the number of clinical trials required for regulatory approval of BCA101 or future product candidates;
- the costs, timing and outcome of regulatory review of BCA101 or any future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of BCA101 or any future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our approach at identifying target patient populations and utilizing our approach to enrich our patient population in our clinical trials;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for BCA101, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, upon the completion of this offering, we expect to incur

additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to BCA101.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash and cash equivalents, the net proceeds from this offering, short-term investments, or any future equity or debt financings and upfront and milestone and royalties payments, if any, received under any future licenses or collaborations. In the future, if we raise additional capital through the sale of equity or convertible debt securities or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties in the future, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Risks Related to Our Business Operations and Industry

Our business is highly dependent on the success of BCA101. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize BCA101, or if we experience delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates and BCA101 remains in clinical or preclinical development. Our future success and ability to generate revenue from BCA101 is dependent on our ability to successfully develop and commercialize BCA101 or any of our future product candidates. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of BCA101 if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, BCA101, including:

- our inability to demonstrate to the satisfaction of the FDA, Health Canada, EMA or other comparable regulatory authorities that BCA101 is safe and effective;
- delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension, termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, Health Canada, the EMA or other comparable regulatory authorities regarding the scope or design of our clinical trials;
- delays or failures in reaching agreement on acceptable terms with clinical trial sites or contract research organizations, or CROs;
- poor effectiveness of BCA101 during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, Health Canada, EMA or other comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our CROs, clinical trial sites, or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, Health Canada, EMA and other comparable regulatory authorities.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. BCA101 or any future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA, Health Canada, the EMA or other regulatory approval or discovering, developing and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our competitors may obtain FDA, Health Canada, the EMA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that

limit our ability to develop or commercialize BCA101. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than BCA101 or, in the case of drugs, have a better safety profile than BCA101. These competitors may also be more successful than us in manufacturing and marketing their products and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience. More specifically, we expect to compete with commercially available therapies for the treatment of head and neck squamous cell carcinoma, or HNSCC, including pembrolizumab (marketed as Keytruda by Merck & Co); the combination of pembrolizumab, platinum chemotherapy and 5-fluorouracil; and the combination of cetuximab (marketed as Erbitux by Eli Lilly in the US and by Merck KGaA outside of the US), platinum chemotherapy and 5-fluorouracil. In addition, there are numerous companies that are developing new treatments for HNSCC, including Merck & Co, Pfizer Inc., Genmab A/S, Exelixis, Inc., Merus N.V., Iovance Biotherapeutics, Inc., Kura Oncology, Inc. and ALX Oncology Holdings, Inc.

Smaller and other early-stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, BCA101 and any future product candidates. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render BCA101 obsolete, less competitive or uneconomical.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize BCA101. Even if BCA101 achieves marketing approval, it may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

Our lead program, BCA101, is initially being developed in HNSCC. We intend to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in recurrent/metastatic HNSCC excluding patients with HPV-positive oropharyngeal squamous cell carcinoma, or OPSCC, and, more generally, we seek to bring transformative bifunctional therapies to patients with solid tumors.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for disorders of the brain and nervous system, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to

capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, health care facilities, physicians or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

Our employees, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, contract manufacturing organizations, or CMOs, and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with FDA, Health Canada, the EMA or other regulations, provide true, complete and accurate information to the FDA, Health Canada, EMA and other comparable regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We, our collaborators and our service providers are subject to a variety of privacy and data security laws, regulations and contractual obligations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with them could expose us to significant fines and other penalties and otherwise harm our business and operations.

The legislative and regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, several jurisdictions, including those in which we operate or collect personal information, have established their own data security and privacy frameworks with which we must comply. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information, could apply to our operations or the operations of our collaborators and service providers. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and impose requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. While pharmaceutical and biotechnology companies are typically not directly regulated by HIPAA, our business may be indirectly impacted by HIPAA in our interactions with providers, payors, and others that have HIPAA compliance obligations. If we are unable to properly protect the privacy and security of protected health information, we could be found to have violated these privacy and security laws and/or breached certain contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant civil and criminal penalties. U.S. Department of Health & Human Services, or HHS, enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

At the state level, numerous states have or are in the process of enacting or considering comprehensive data privacy and security laws, rules and regulations while other states have focused on more narrow aspects of

privacy. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In the state of Washington, for example, the My Health My Data Act, which has a private right of action that further increases the relevant compliance risk, requires regulated entities to obtain consent to collect health-related information and grants consumers certain rights, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

If we conduct clinical trials in the European Economic Area, or the EEA, and/or the United Kingdom, or the U.K., we will be subject to additional, more stringent privacy laws in other jurisdictions, such as the General Data Protection Regulation, or the EU GDPR, as well as other national data protection legislation in force in relevant European Union, or EU, member states. The EU GDPR imposes strict regulations and establishes a series of requirements regarding the collection, transfer, storage and processing of personal data. Following the U.K.'s withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the U.K. and EU as of January 1, 2021, the EU GDPR has been incorporated into U.K. domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019, or the U.K. GDPR, and, together with the EU GDPR, the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including strict requirements relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required strict requirements relating to obtaining consent of individuals, disclosures about how personal information is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities, documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA or the U.K., including the United States (see below), and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Non-compliance could also result in the imposition of orders to stop data processing activities, which could have a material adverse effect on our business, financial position and results of operations.

When subject to GDPR, we will be required to put in place mechanisms to ensure compliance, including as implemented by national laws of EU Member States which may partially deviate from the EU GDPR and impose different and more restrictive obligations from country to country. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European and U.K. activities.

The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but, currently, aligned to the EU's data protection regime. The European Commission, or the EC, has adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EEA remain unaffected. The U.K. Government has also introduced a Data Protection and Digital Information Bill (or the UK Bill) into the UK legislative process with the intention for this bill to reform the U.K.'s data protection regime which will likely have the effect of further altering the similarities between the U.K. and EU data protection regime.

In addition, we will be required to implement adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with the GDPR. In some cases, we may rely upon the EC's approved standard contractual clauses to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the GDPR). The U.K. is not subject to the EC's standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Addendum/Agreement, which enables transfers from the U.K. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U.S. have adopted its adequacy decision for the EU U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. Moreover, the U.K. Government adopted the Data Protection (Adequacy) Regulations 2023, also referred to as the "UK-U.S. Data Bridge", which, since 12 October 2023 allows companies to transfer personal data from the U.K. to the U.S. on the basis of the Framework. This provides a further avenue to ensuring transfers to the U.S. are carried out in line with GDPR. However, the long-term validity of the Framework remains uncertain and it has already been challenged before European courts.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our proprietary information, the value of BCA101 could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and/or confidential know-how, unpatented know-how and/or other proprietary information. We may rely on other proprietary rights, including protection of trade secrets, confidential know-how, unpatented know-how and/or other proprietary information to protect BCA101, especially where patent protection is believed to be of limited value. However, trade secrets and/or confidential know-how are difficult to maintain as confidential. To maintain the confidentiality of this type of information, it is our policy to enter into confidentiality agreements with our employees, consultants, advisors, collaborators, contractors (including CROs), and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual(s) or made known to the individual by us during the course of the individual's relationship or work with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms, intentionally or unintentionally. Thus, despite such agreement, such inventions may become assigned to third

parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, contractors or others use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us or a current or future licensor is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. The disclosure of our trade secrets could impair our competitive position and may materially harm our business, financial condition and results of operations.

Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements and theft of trade secret claims may vary from jurisdiction to jurisdiction. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. As such, adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. Such persons may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, such persons could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to guarantee our freedom to operate, we may also decide to publish some know-how to prevent others from obtaining patent rights covering such know-how.

The use of new and evolving technologies, such as artificial intelligence, or AI, in our operations may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We may integrate AI into our operations, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act, or the AI Act—the world's first comprehensive AI law — is anticipated to enter into force in 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we deploy AI systems that are governed by the AI Act, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to the Discovery and Development of BCA101 or Future Product Candidates

Our business is dependent on our ability to advance BCA101 and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts as BCA101 remains in clinical development. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual regulatory approval and commercialization of our current products or future product candidates we develop, which may never occur. Our current product candidate, BCA101, and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States, Canada and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of BCA101 and any future product candidates will depend on several factors, including the following:

- timely and successful completion of our clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- our plans to successfully submit new Investigational New Drug, or IND applications with the FDA for BCA101 and any future product candidates;
- our ability to complete preclinical studies for BCA101 or any future product candidates;
- successful enrollment in, and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to establish agreements with third-party manufacturers on a timely and cost-efficient manner;
- whether we are required by the FDA, Health Canada, the EMA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;

- our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize BCA101 or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that BCA101 or any future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of BCA101 or any future product candidate, we may not be able to continue our business operations or achieve profitability.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize BCA101 and any future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans and have a favorable risk-benefit profile. Clinical trials are expensive and can take many years to complete, with a highly uncertain outcome. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We cannot be certain the ongoing and planned preclinical studies or clinical trials for BCA101 or any other future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA, Health Canada, the EMA or other regulatory authorities, Institutional Review Boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA, Health Canada, the EMA or regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;

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- the number of patients required for clinical trials may be larger than we anticipate, or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications and clinical trial subjects;
- enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;
- the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- we may need to change the manufacturing site and potentially the CMO for our product candidates from those that are able to produce clinical supply for our clinical trials to those with the capacity and ability to perform commercial manufacturing and/or the production of clinical material for our later stage clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees or the Data and Safety Monitoring Board, or the DSMB, for such trial or by the FDA, Health Canada, the EMA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, Health Canada, the EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. The FDA, Health Canada, the EMA or other regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Further, the FDA, Health Canada, the EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials. For example, we are conducting and may in the future conduct additional “open-label” clinical trials. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that

may exaggerate any therapeutic effect as patients may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. For example, in our ongoing Phase 1/1b trial, objective response rate as determined using RECIST 1.1 criteria is assessed by the trial investigators who may be aware of the trial treatment, patient history or other information that could impact their choices in applying the rules and conventions of RECIST 1.1. The published literature demonstrates a consistent decrease in response rate when investigator assessed response rates are verified by independent radiology review.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or other compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing BCA101 or any future product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates.

Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early.

Preclinical development is uncertain. Any preclinical programs we pursue may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

The risk of failure for product candidates still in the discovery or preclinical stage is high. In addition, any one or more of our product candidates that have not yet entered the clinic may never advance into clinical development. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of BCA101 or any future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, Health Canada, the EMA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design; and
- the FDA, Health Canada, the EMA or foreign regulatory authorities not permitting the reliance on preclinical or other data from published scientific literature.

We are currently conducting, and may in the future conduct, clinical trials for BCA101 or any future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting, and may in the future conduct, clinical trials for BCA101 or any future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are currently conducting clinical trials in the U.S. and Canada, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA, Health Canada, the EMA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations, and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, Health Canada, the EMA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA, Health Canada, the EMA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in BCA101 or any future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to (i) test safety, (ii) study pharmacokinetics and pharmacodynamics and (iii) understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, BCA101 or any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Interim data and results from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Furthermore, third parties, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to disclose. If regulatory authorities disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

BCA101 or any future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biological products, use of BCA101 or any future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to product therapeutics and bispecifics in oncology.

EGFR-targeted drugs have been observed to cause side effects, predominantly related to skin toxicity and rash, and TGF-b inhibitors have been shown to have side effects primarily related to bleeding. While we have observed these side effects during our studies, the severity of these has been minimal but additional or more

severe treatment-related side effects may emerge at a later time in our trials. In addition to any potential side effects caused by the product or product candidate, the administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated. Additionally, we may be required to repeat or conduct additional clinical trials or nonclinical studies for our product candidates beyond those that we currently contemplate. There can be no assurance that BCA101 or any future product candidates will not demonstrate unacceptable toxicities in later testing that may render it unsafe or intolerable.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA, Health Canada, the EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although BCA101 and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Antibody therapeutics and bispecifics and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that BCA101 is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If BCA101 or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we intend to pursue our product candidates in combination with other therapies and may develop future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone.

Even if we successfully advance our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

Even if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may limit, suspend, or withdraw their approval of the product or may refuse to approve supplemental applications for such product;

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- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our antibody therapeutic development approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the trial results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also expect to continue to rely on third parties to conduct our clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for biologics license application, or BLA, submission and FDA approval of BCA101 or any future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

If we or our collaborators encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until the trial’s conclusion, including any follow-up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the nature and size of the patient population required for analysis of the trial’s primary endpoints and the process for identifying patients;
- the number and location of participating clinical sites or patients;

- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies;
- our ability to obtain and maintain patient informed consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial.

Delays or difficulties in patient enrollment may result in increased costs or may affect the timing, outcome or completion of clinical trials, which would adversely affect our ability to advance the development of the product candidates we develop.

Failure to successfully develop and commercialize companion diagnostics with third party contractors for use with our product candidates could harm our ability to commercialize our product candidates.

We plan to develop, or engage third parties to develop, companion diagnostics for our product candidates where appropriate. At least in some cases, the FDA and similar regulatory authorities outside the United States may request or require the development and regulatory approval of a companion diagnostic as a condition to approving one or more of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. We do not have experience or capabilities in developing or commercializing diagnostics and are relying, and in the future plan to continue to rely, in large part on third parties to perform these functions.

In most cases, we will likely outsource the development, production and commercialization of companion diagnostics to third parties. By outsourcing these companion diagnostics to third parties, we become dependent on the efforts of our third-party contractors to successfully develop and commercialize these companion diagnostics. Our contractors:

- may not perform their obligations as expected;
- may encounter production difficulties that could constrain the supply of the companion diagnostic;
- may have difficulties gaining acceptance of the use of the companion diagnostic in the clinical community;
- may not commit sufficient resources to the marketing and distribution of such product; and
- may terminate their relationship with us.

We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related product candidates. Further, if any companion diagnostic for use with one of our product candidates fails to gain market acceptance, our ability to derive revenues from sales of such product candidate could be harmed. If our third-party contractors fail to commercialize such companion diagnostic, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with such product candidate or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of such product candidate.

Risks Related to Our Dependence on and Work with Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct monitor and manage data for our preclinical studies and clinical trials. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the competent authorities of the member states of the EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, Health Canada, the EMA or comparable foreign regulatory authorities, who may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with the product candidate produced under FDA's current good manufacturing practice, or cGMP, regulations or similar foreign regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these principal investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the

quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We currently and may depend on other third-party collaborators for the discovery, development and commercialization of BCA101 and any of our future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have entered into collaborations with MSD International GmbH, or MSDIG, and MSD International Business GmbH, or MSDIB, and collectively with MSDIG, MSD and Biocon Ltd, or Biocon. In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. Our current and potential future collaborations involving our product candidates may pose various risks to us, including:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

For future collaborations, if we enter into such collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our

timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies such transaction. Any of the factors set forth above, among others, could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

We currently have established collaborations and may seek to establish future collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of BCA101 and any of our future product candidates will require substantial additional cash to fund expenses. We currently collaborate with pharmaceutical and biotechnology companies with respect to development and potential commercialization of BCA101, and we may also do so with any future product candidates. These relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA, Health Canada, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved product candidate and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, Health Canada, the EMA or comparable foreign regulatory authorities following inspection of their facilities and procedures to manufacture our product candidates, fail to provide us with sufficient quantities of a product candidate or fail to do so at acceptable timing, quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.

We rely on and expect to continue to rely on third-party CMOs for the supply of cGMP-grade clinical trial materials and commercial quantities of our product candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture product candidates ourselves. The facilities used by our CMOs to manufacture our product candidates must be approved by the FDA foreign regulatory authorities pursuant to inspections that will be conducted after we submit our Biologics License Application, or BLA, to the FDA, or similar applications to foreign regulatory authorities. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP or similar foreign requirements for the manufacture of our product candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, Health Canada, the EMA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities or may result in delay of our ability to obtain marketing authorization, if any, of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, Health Canada, the EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

We rely on our CMOs to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials, and will rely on our existing and future collaborators to purchase from third-party suppliers the materials necessary to develop and produce our product candidates for future clinical trials and, upon approval, our products for commercialization. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. Apart from contractual measures, we do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers or manufacturers paid by our collaborators. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of an product candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of an product candidate, or the raw material components thereof, for a planned or

an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

In addition, the manufacturing of our product candidates is expensive and time-consuming, and generally requires more complex processes than those associated with small-molecule drugs. If we are successful in obtaining regulatory approval for any of our product candidates, we might have limited quantities of such product candidates available to us in connection with a potential commercial launch, and these supplies may be further limited by our ongoing clinical development activities. If our manufacturers, collaborators or we are unable to purchase or produce sufficient quantities of raw materials or of our product candidates after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which in either case, would impair our ability to generate revenues from the sale of our product candidates.

We rely on our manufacturers and other subcontractors to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If our manufacturers or other subcontractors fail to acquire the proper licenses or otherwise infringe third party proprietary rights in the course of completing their contractual obligations to us, we may have to find alternative manufacturers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

The operations of our suppliers, many of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

We currently rely on and engage third-party manufacturers to provide all of the drug substance and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we primarily rely on one manufacturer, WuXi Biologics (Hong Kong) Limited, or WuXi Bio, for the production of product necessary to complete our ongoing clinical trials. If a replacement manufacturer became necessary in the future, we may incur added costs and delays in identifying and qualifying another manufacturer. We currently do not have any long-term supply agreements in place, though we intend to enter into such agreements as well as evaluate additional product manufacturing sources in the future. As a result of our dependence on ex-U.S. suppliers, we are subject to risks associated with doing business abroad, including:

- geopolitical tensions, political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured, particularly China;
- the imposition of new laws and regulations, including those relating to labor conditions, safety standards, information and data transfer, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate, including China, pursuant to our master supply agreement with WuXi Bio;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, Health Canada, the EMA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trade secret protection, in some countries, particularly China;
- disruptions in operations due to global, regional, or local epidemics, pandemics, public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

If enacted, legislation known as the BIOSECURE Act, which was introduced by Congress, would prohibit U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern” in the performance of that contract. It would also prohibit recipients of loan or grant funding from U.S. federal agencies from using loan or grant funds to procure, obtain or use any biotechnology equipment or services produced or provided by a “biotechnology company of concern.” This legislation would restrict the ability of biopharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act. The current version of the BIOSECURE Act introduced in the House of Representatives names WuXi Bio as a “biotechnology company of concern.” If approved, the BIOSECURE Act in its current form would not prevent us from sourcing drug product from WuXi Bio for clinical use. Depending on the final language of the BIOSECURE Act, and how the law is interpreted by U.S. federal agencies, however, we could be potentially restricted from pursuing U.S. federal government business or government reimbursement for our products if we enter long-term commercial arrangements with WuXi Bio or other suppliers or partners identified as “biotechnology companies of concern.” Additionally, the legislation could adversely impact WuXi Bio’s operations or financial position, which, in turn, could impact its and ability to supply us with product in the future. We may also face additional manufacturing and supply-chain risks due to the regulatory and political structure of China, or due to the deterioration of the relationship between China and the U.S., including but not limited to potential sanctions imposed by the U.S. government on WuXi Bio, or any of the other countries in which our products are marketed.

These and other factors beyond our control could interrupt our suppliers’ production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all and inhibit our supplier’ ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations and prospects.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

We may need to maintain licenses for drug substances from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use any cell line and raw materials in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those drug substances from those third parties. If we are unable to gain or continue to access rights to these drug substances prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate drug substances, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired drug substances on commercially reasonable terms or develop suitable alternate drug substances, we may not be able to commercialize product candidates from these programs.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval (or maintain approval) may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, has required and will require us to continue to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options; Project Equity, which is an initiative to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended; and Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance. We are considering these and other policy changes as they relate to our programs.

We have not obtained regulatory approval for any product candidate. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receives regulatory approval of a BLA, from the FDA. It is possible that BCA101 or any future product candidates will not obtain regulatory approval from the FDA, Health Canada, the EMA or comparable foreign regulatory authorities.

BCA101 and any future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, Health Canada, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, Health Canada, the EMA or comparable foreign regulatory authorities that a product candidate has an acceptable risk-benefit profile in the proposed indication;
- we may be unable to demonstrate to the satisfaction of the FDA, Health Canada, the EMA or comparable foreign regulatory authorities that the facility in which a product candidate is manufactured meets standards designed to assure that the product candidate continues to be safe, pure, and potent;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, Health Canada, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, Health Canada, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA, Health Canada, the EMA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and
- the FDA, Health Canada, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, Health Canada, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials or other post-marketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates. Even if we obtain regulatory approval for our product candidates, we will be required to submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve such applications or supplements.

In addition, the FDA, Health Canada, the EMA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for biological products or modifications to approved biological products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with GCP requirements, which are regulations and guidelines enforced by the FDA, Health Canada, the EMA and comparable foreign regulatory authorities.

Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethical committees at the trial sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or trial protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to trial subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- BCA101 may not appear to offer benefits over current therapies; or
- the quality or stability of BCA101 may fall below acceptable standards.

We intend to develop our product candidates in part in combination with other therapies and may develop our future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

We intend to develop our product candidates in part in combination with other therapies, including BCA101 in combination with pembrolizumab as a treatment for HNSCC and SCAC, and may develop BCA101 and any future product candidates in combination with one or more currently approved cancer therapies. These combinations have not been previously tested in the clinic and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products.

Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, Health Canada, the EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer diseases, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate BCA101 or any future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, Health Canada, the EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, Health Canada, the EMA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biological products we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Even if we receive marketing approval of BCA101, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Any marketing approvals that we may receive for BCA101 or any future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, Health Canada, the EMA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, tracking and tracing event and deviation reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP, for any clinical trials that we may conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

- suspension of, or imposition of restrictions on, the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- Warning letters or untitled letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we file, or suspension or revocation of approved biologics licenses;
- product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and
- permanent injunctions and consent decrees including the imposition of civil or criminal penalties.

Given the nature of biological products manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, an approved product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, or off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm's product communication is consistent with the FDA-required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

The FDA and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

While we intend to seek designations for our potential product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our potential product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities and priority review.

However, there can be no assurance that we will successfully obtain such designations for any potential product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our potential product candidates, there can be no assurance that we will realize their intended benefits. For example, we may seek fast-track designation for some of our potential product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy nonclinical or clinical data demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for fast-track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast-track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast-track designation if it believes that the designation is no longer supported by data from our clinical development program.

Additionally, we may seek a breakthrough therapy designation for some of our potential product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion

of the FDA. Accordingly, even if we believe one of our potential product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our potential product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for the product candidates that we may develop. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may not be able to obtain or maintain orphan drug designations for our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. For example, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We may not be able to obtain orphan drug designation for any indications for our product candidates, and we may not be able to maintain such designations if granted.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same biologic for the same indications for seven years. Even if we are able to obtain orphan drug designation or orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if, among other things, the FDA concludes that the later drug is clinically superior, if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Even if we receive orphan drug designation or orphan drug exclusivity for any of our product candidates, there is no guarantee that we will enjoy the benefits of such designations or exclusivity periods.

The decision of the U.S. Court of Appeals for the 11th Circuit in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021) has created uncertainty regarding the scope of orphan drug exclusivity. Although the FDA subsequently announced that it intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order and continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, it is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

While we may seek accelerated approval for some of our product candidates, we may not be able to obtain it as the sufficiency of our clinical trial results for accelerated approval are subject to the FDA's discretion.

We plan to seek approval for BCA101 under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. For more information, see the section titled "*Business—Government Regulation—Review and Approval for Licensing Biologics in the United States—Expedited Review Programs.*"

Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Moreover, even if we received accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

Risks Related to Commercialization

The commercial success of BCA101 or any future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

BCA101 and any future product candidates may not be commercially successful. Even if BCA101 or any future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of BCA101 or any future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more established products;
- the indications for which BCA101 or any future product candidates are approved, if any;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;

- the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs;
- the effectiveness of our or any current or future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If BCA101 or any future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The market opportunities for BCA101 or any future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The number of patients who receive second- and third-line treatment is significantly smaller than the number of patients who receive first-line treatment, and the prognosis of patients who receive second- or third-line treatment is often poorer than that of patients who receive first-line treatment.

We may initially seek approval for any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer or autoimmune diseases we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for BCA101 or any future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

If approved, our product candidates that are regulated as biological products, or biologics, may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, established an abbreviated pathway for the approval of biosimilar and interchangeable biologics with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of

exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data and is not submitted as a biosimilar application. Certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. The law is complex and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

Obtaining and maintaining marketing approval of BCA101 and any future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of BCA101 and any future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of BCA101 and any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We may enter into agreements with third parties to sell, distribute and/or market BCA101 if we obtain regulatory approval, which may adversely affect our ability to generate revenues.

Given the development stage of BCA101, we have no experience in sales, marketing and distribution of biotech products. However, if BCA101 obtains marketing approval, we might intend to develop sales and marketing capacity, either alone or with partners, or rely upon the sales and marketing capabilities of our partners.

Outsourcing sales, distribution and marketing may subject us to a variety of risks, including:

- our inability to exercise direct control over sales, distribution and marketing activities and personnel;
- potential failure or inability of contracted sales personnel to successfully market our products to physicians; and
- potential disputes with third parties concerning distribution, sales and marketing expenses, calculation of royalties, and sales and marketing strategies.

If we are unable to partner with a third party that has adequate sales, marketing, and distribution capabilities, we may have difficulty commercializing our BCA101 which would adversely affect our business, financial condition, and ability to generate product revenues.

Off-label use or misuse of BCA101 may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If BCA101 is approved by the FDA, we may only promote or market BCA101 in a manner consistent with its FDA-approved labeling. We will train our marketing and sales force against promoting BCA101 for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using BCA101 off-label, when in the physician’s independent professional medical judgment, he or she deems it appropriate. Furthermore, the use of BCA101 for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of BCA101 could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use BCA101 for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

We are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations

described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of BCA101 or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends, in part, on obtaining and maintaining patents and other forms of intellectual property rights for BCA101, including BCA101 and any future product candidates, methods used to produce, purify, and manufacture those product candidates, and methods of utilizing the product candidates, including methods for treating patients, among other aspects of BCA101 or on licensing-in such rights. Failure to protect or to obtain, maintain, or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market BCA101.

Our strategy depends in part on our ability to identify and seek patent protection for our discoveries. The patent prosecution process is time-consuming and expensive, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our current or future licensors, licensees, or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them.

The standards which the United States Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change in the future. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, the issuance, scope, validity, enforceability, and commercial value of our and our current or future licensors', licensees' or collaborators' current and future patent rights are highly uncertain. We cannot predict whether additional patents protecting BCA101 will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued which protect BCA101 or other technology, in whole or in part, or which effectively prevent others from commercializing competitive products and technology. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of our or our current or future licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, or have issued and even if such patents cover a product candidate, and/or other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, litigation, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable. Our and our current and future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issue from such application(s), and then only to the extent the issued claims cover the technology in the relevant jurisdiction.

Patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries. As such, we cannot be certain that we or our licensors were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize BCA101 without providing any notice or compensation to us or may limit the scope of patent protection that we or our licensors are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on BCA101 in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States

could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. As such, we will not file for patent protection in all national and regional jurisdictions in the world where such protection may be available.

Accordingly, competitors may use our and our existing or future licensors', licensees' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our existing or future licensors, licensees or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with BCA101 or other technologies, and our and our existing or future licensors', licensees' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, and the requirements for patentability differ, in varying degrees, from country to country, and the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Such issues may make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Furthermore, proceedings to enforce our patent rights and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Issued patents covering BCA101 and related technology could be found invalid or unenforceable if challenged in court or before a patent office. We may become involved in lawsuits involving our intellectual property, including patents, to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Issued patents may be challenged, narrowed, invalidated or circumvented. We may from time to time need to resort or become a party to litigation (or other adversarial proceeding) to enforce or defend any patents or

other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties in the U.S. and in other jurisdictions. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our product without being enjoined, required to pay us any license fees, or compensate us for lost profits or reasonable royalty. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize technology covered by our patents we seek to enforce, such as those covering BCA101 and related methods, among other technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering BCA101 or other technology, the defendant could counterclaim that our patent is invalid and/or unenforceable, which is commonplace in patent litigation in the United States and other foreign jurisdictions. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for patentability, for example, lack of utility, novelty, obviousness, non-enablement or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the USPTO or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the USPTO. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on BCA101 or other technology. Such a loss of patent protection could have a material adverse impact on our business. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Patents and other intellectual property rights also will not protect BCA101 if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if such litigation (or other adversarial proceedings or disputes) is resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings and the legal costs associated with them, could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unsuccessful in defending against any claims by competitors or others that we are infringing upon their intellectual property rights, our business could be materially harmed.

Our commercial success will depend, in part, on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale or import a product candidate, a future approved product, or impair our competitive position. We are aware of third party issued patents and/or pending patent applications, including in the U.S., that could be alleged as covering BCA101, irrespective of the merits of any such allegation. Although we believe that these patents are not infringed, and/or are invalid and/or unenforceable, if a court should find that they cover a product candidate and we are unable to invalidate such patents, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

We believe that if such patents or patent applications were asserted against us, we would have counterclaims and defenses against such claims, including non-infringement, the affirmative defense of safe harbor designed to protect activity undertaken to obtain federal regulatory approval of a drug, including under 35 U.S.C. § 271(e) and similar foreign exceptions to infringement, and defenses concerning patent invalidity and/or unenforceability. However, if such counterclaims and defenses were not successful and such patents were successfully asserted against us such that they are found to be valid and enforceable, and infringed, unless we obtain a license to such patents, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize BCA101. We could also be required to pay substantial damages. We cannot assure you that we will ultimately prevail if any of this third-party intellectual property is asserted against us.

In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, opposition or other proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits (or other proceedings) would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

In addition, if the breadth or strength of protection provided by our or our present or future licensors', collaborators' or partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize BCA101 or any future product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third party intellectual property right holders, including our competitors, may actively bring infringement claims against us. We may not be able to successfully settle, license on commercially acceptable terms or otherwise resolve such potential infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing any approved products. If we fail in any such dispute, in addition to being forced to potentially pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing our product candidates that are held to be

infringing or be forced to redesign our product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

The biotechnology industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing BCA101 to market and be precluded from manufacturing or selling BCA101.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

It is also possible that in our evaluation of third-party intellectual property, we failed to identify relevant patents or applications. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of BCA101 in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market BCA101. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover BCA101 or related technology. We cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims.

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are currently party to intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various obligations on us. For example, we have entered into patent and know-how license agreements that grant us the right to use certain technologies related to our clinical product candidate and related methods. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

We may be unsuccessful in licensing or acquiring third-party intellectual property that may be required to develop and commercialize BCA101.

We have rights, through patents that we have in-licensed or own, to the intellectual property to develop BCA101. Because our programs may involve additional product candidates, that may require the use of intellectual property or proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. We may be unable to acquire or in-license any third-party intellectual property or proprietary rights or to do so on commercially reasonable terms. For example, we sometimes collaborate with public or private academic institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the strategic collaboration. Regardless of such option, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us, and the institution may license such intellectual property rights to third parties, potentially blocking our ability to pursue our development and commercialization plans. The same situation may occur with a present or future development partner.

The licensing and acquisition of third-party intellectual property and proprietary rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property and proprietary rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size and greater capital resources and development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property and proprietary rights to us.

If we are unable to successfully acquire or in-license rights to required third-party intellectual property and proprietary rights or maintain our intellectual property and proprietary rights, we may have to cease development of the relevant the relevant program, product or product candidate, which could have a material adverse effect on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution and post grant or issuance. We employ reputable law firms and other professionals to help us comply. Additionally, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We rely on our outside counsel or our agents to pay these fees when due. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant

jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If such an event were to occur, it could have a material adverse effect on our business. In addition, we may be responsible for the payment of patent fees for patent rights that we license from third parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights. If we or our existing or future licensors fail to maintain the patents and patent applications covering BCA101, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering BCA101, our business may be materially harmed.

Patents typically have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, not including potential patent term extensions or adjustments that may be available in the U.S., and under comparable laws applicable outside the U.S., where certain conditions are met. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering BCA101 are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including biosimilar medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, causing our revenue from applicable products to be reduced, possibly materially, and potentially harming our ability to recover our investment in such product or obtain a reasonable return on that investment.

Depending upon the timing, duration, and conditions of FDA marketing approval of BCA101, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at other biotechnology or pharmaceutical companies, universities, and/or research institutions and the like, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to BCA101, are rightfully owned by their former or concurrent employer.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to

a third party, and we could be required to obtain a license from such third party to commercialize BCA101. Such a license may not be available on commercially reasonable terms or at all.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Healthcare, Insurance and Legal Matters

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of BCA101.

We face an inherent risk of product liability exposure related to the testing of BCA101 in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate we may develop;
- withdrawal of trial participants;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any product candidates that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for BCA101, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

The successful commercialization of BCA101 or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs including but not limited to Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as BCA101 or any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. For more information, see the section titled “*Business—Government Regulation—Pharmaceutical Coverage, Pricing and Reimbursement.*”

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and offer to reimburse patients only for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for BCA101 or any future product candidates.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in

these rules and regulations are likely. For products administered under the supervision of a physician (including products administered in the clinical setting), obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the administration of the product, or the treatment or procedure in which the product is used, may not be available, which may impact physician utilization.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of BCA101 or any future product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare and Medicaid beneficiaries, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidate may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, and plan to market, sell and distribute any products for which we obtain regulatory approval. For more information, see the section titled “*Business—Government Regulation—Other U.S. Healthcare Laws.*”

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations

or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be noncompliant with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs. We plan to implement a corporate compliance program designed to identify, prevent and mitigate risk through the implementation of policies and procedures, training, and auditing and monitoring. We expect to devote resources to implement, maintain, administer and expand the compliance program as necessary. We cannot be certain, however, that our compliance program will ensure compliance with the various complex laws and regulations to which we are subject now or in the future.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize BCA101, if approved, or any future product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and biologics and affect our ability to profitably sell BCA101 or any future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For more information, see the section titled “*Business—Government Regulation—Current and Future U.S. Healthcare Reform Legislation.*”

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for BCA101 and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing laws and other federal and state healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our potential products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize BCA101 or any future product candidates, if approved.

Failure to comply with laws and regulations related to the protection of research subjects could result in fines, penalties, and litigation, and have a material adverse effect upon our business.

We may be subject to regulation under international, federal, state, and local laws and regulations relating to the protection of research subjects. Federally funded human-subject research in the United States, including the

collection of identifiable human biospecimens, is governed by 45 CFR Part 46, also known as the Health and Human Services Policy for Protection of Human Research Subjects or the “Common Rule.” Use of biospecimens in certain other research is subject to FDA regulations for the Protection of Human Subjects and Institutional Review Boards at 21 CFR Parts 50 and 56. Research funded by the National Institutes of Health, or NIH, may be subject to grant or contract requirements, as well as NIH Certificates of Confidentiality. When collecting specimens for research in the United States, our company and its collection sites are responsible for ensuring that specimens are collected in accordance with these regulations. In addition, other countries have their own regulations around the ethical collection of human specimens for research. While we believe that we are in compliance with these laws, we may not be aware of all such laws or may fail to properly audit and identify gaps in compliance. Similarly, we may find errors in our product candidates and processes and may fail to properly match the compliance requirements of our researchers to the compliance requirements of our suppliers. Failure of our company or our suppliers to comply with international, federal, state, and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties, and/or other enforcement actions which could have a material adverse effect on our business.

Risks Related to Manufacturing of Our Product Candidates

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. In addition, we may need a different CMO for manufacturing BCA101 or any future product candidates for commercial supply needs. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause BCA101 or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of BCA101 and jeopardize our ability to commence sales and generate revenue.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of BCA101.

The process of manufacturing product therapeutics and bispecifics, including BCA101, is complex, time-consuming, highly regulated and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination; the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task and involves additional risks, including cost overruns, process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of sufficient quantity of raw materials. Even if we obtain regulatory approval for any of our product candidates, manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause BCA101 to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to Employee Matters and Managing Growth

Our ability to develop product candidates, leverage our potential and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Additionally, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. The loss of services of any of these individuals could delay or prevent the successful development of BCA101, completion of our planned clinical trials or the commercialization of BCA101.

Our success also depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of our product candidates. Given the specialized nature of dual-action biologics and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel, in particular our scientists, would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

As our development plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- managing our internal development efforts effectively, including the clinical and FDA review process for BCA101 and any other future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize BCA101 and any future product candidates we develop, will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of BCA101 or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize BCA101 or any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to this Offering and Ownership of Our Common Stock

There has been no prior public market for our common stock, and an active trading market may not develop or be sustained.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock may vary from the market price of our common stock following this offering. An active or liquid market in our common stock may not develop upon closing of this offering or, if it does develop, it may not be sustainable. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products, or technologies by using our common stock as consideration.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment, completion or results of our current or future preclinical and clinical trials for BCA101;
- any delay in identifying and advancing a clinical candidate for our other programs;

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- any delay in our regulatory filings for BCA101 and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval or potential accelerated approval of BCA101 or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to BCA101, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize BCA101, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to BCA101 or any future product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or BCA101 in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;

- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to BCA101 or any future product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing BCA101, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for BCA101 or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for BCA101 from regulatory authorities in the United States and internationally;
- exchange rate fluctuations;
- coverage and reimbursement policies with respect to BCA101, if approved, and potential future drugs that compete with our products; and
- the level of demand for BCA101, if approved, may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our future revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we

provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors, principal stockholders and their respective affiliates own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of _____, 2024, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately _____% of our common stock and, upon the completion of this offering, that same group will hold approximately _____% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our preferred stock into shares of our common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. In addition, certain of our principal stockholders, including RA Capital and TPG LSA, have designated certain members of our board of directors. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Future sales of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the completion of this offering, _____ shares of common stock will be outstanding (or _____ shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of December 31, 2023.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining _____ shares, or _____% of our outstanding shares of common stock

following this offering, is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “*Shares Eligible for Future Sale.*”

Upon the completion of this offering, the holders of approximately _____ shares, or _____ % of our outstanding shares following this offering, of our common stock will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under the section titled “*Underwriting.*”

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We will have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We currently intend to use our cash resources for clinical development of BCA101, the advancement of future preclinical and discovery programs, and for working capital and other general corporate purposes. Although we currently intend to use our cash resources in such a manner, we will have broad discretion in their application, including for any of the purposes described in the section titled “*Use of Proceeds,*” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management’s judgment with only limited information about our specific intentions for the use of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. Our failure to apply these funds effectively could affect our ability to continue to develop and commercialize BCA101. Pending their use, we may invest our cash resources in a manner that does not produce income or loses value.

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately following the completion of this offering. If you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma as adjusted net tangible book value per share of \$ _____ per share as of December 31, 2023. That is because the price that you pay will be substantially greater than the pro forma as adjusted net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution if the underwriters exercise their option to purchase

additional shares in this offering, when those holding stock options exercise their right to purchase common stock under our equity incentive plans, upon the vesting of outstanding restricted stock awards or when we otherwise issue additional shares of common stock. For additional details see the section titled “Dilution.”

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent our existing stockholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our common stock after this offering, which is the number of shares of common stock that are not held by our officers, directors and affiliated stockholders. A reduction in the public float could reduce the number of shares of common stock that can be traded at any given time, which could adversely impact the liquidity of our common stock and depress the price at which you may be able to sell shares of common stock purchased in this offering.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Our fifth amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, will contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;

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- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our third amended and restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our bylaws that will become effective upon the effectiveness of this registration statement designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws that will become effective upon the completion of this offering provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders’ ability to bring a claim in a forum that

they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were “facially valid” under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.

If our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq’s listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq’s listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders’ ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

Other General Risks

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts between Russia and Ukraine, and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. For example, there has been proposed U.S. legislation that may restrict the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We continue to assess the legislation as it develops to determine whether it could have an effect on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We, or the third parties upon whom we depend, may be adversely affected by natural disasters, public health crises or other business interruptions and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, public health crisis or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results or delaying our ability to obtain regulatory approval for BCA101, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer cybersecurity incidents or breaches, which could adversely affect our business.

Despite the implementation of security measures, our information technology systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, computer viruses, social engineering (e.g., phishing attacks) and malware (e.g., ransomware malicious software), fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a result of a continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we continue to make investments to improve the protection of data and information technology, including in the hiring of IT personnel, periodic cyber security awareness trainings, and improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or cybersecurity incidents or breaches.

We and certain of our service providers are from time to time subject to cyberattack attempts or incidents and cybersecurity incidents. Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any significant cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to cybersecurity incident or breach notification requirements, regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties, result in substantial costs and distract management. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price and shareholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a cybersecurity breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research institution collaborators for research and development of BCA101 and other third parties for the manufacture of BCA101 and to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or cybersecurity incident or breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of BCA101 could be delayed, result in substantial costs and distract management.

We are eligible to be treated as an “emerging growth company” and a “smaller reporting company” and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements in this prospectus. We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a “large accelerated filer,” which occurs when the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30, or if we have total annual gross revenue of \$1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” disclosure in this prospectus;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

Even after we no longer qualify as an emerging growth company, we could still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following completion of this initial public offering. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2023, we had approximately \$80.4 million of federal net operating losses, or NOLs. Federal NOLs generated in taxable years since inception, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of our taxable income. As of December 31, 2023, we had approximately \$75.6 million of state NOLs. Of the state NOLs, some are of indefinite life, but most are of

definite life with various expiration dates, beginning in 2039. As of December 31, 2023, we had approximately \$1.3 million of federal research and development tax credit carryforwards. Federal tax credit carryforwards expire at various dates, beginning in 2040. As of December 31, 2023, we had approximately \$0.3 million of state research and development tax credit carryforwards. The state tax credits, which have various carryforward rules, begin to expire in 2035.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by “5 percent shareholders” over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes as a result of our acquisitions of assets and as a result of this offering and/or subsequent shifts in our stock ownership (some of which are outside our control). There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We may become involved in securities class action litigation that could divert management’s attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management’s attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled “*Prospectus Summary*,” “*Risk Factors*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” and “*Business*,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation timing, progress, results and cost of BCA101, including the Phase 2/3 trial in head and neck squamous cell carcinoma and the potential expansion Phase 1 trial in additional head and neck squamous cell carcinoma patient populations, as well as our research and development programs and our current and future preclinical and clinical studies;
- the ability and the potential to secure pembrolizumab for our clinical trials and successfully manufacture our drug substances and BCA101 for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability of clinical trials to demonstrate safety and efficacy of BCA101, and other positive results;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of BCA101;
- the timing, scope and likelihood of regulatory filings and approvals, for BCA101 and future product candidates, including the timing of INDs and final FDA approval of BCA101 or any future product candidate;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our estimates of the number of patients that we will enroll and our ability to initiate, recruit and enroll patients in and conduct and successfully complete our clinical trials at the pace that we project;
- our ability to maintain and further develop the specific shipping, storage, handling and administration of BCA101 at the clinical sites;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and BCA101;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of BCA101;
- our ability to obtain and maintain regulatory approval of BCA101;
- our ability to commercialize BCA101, if approved;
- the pricing and reimbursement of BCA101, if approved;
- the implementation of our business model, and strategic plans for our business, BCA101 and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering BCA101 and other product candidate we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- estimates of our future expenses, revenues and capital requirements and our needs for additional financing;

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- future agreements with third parties in connection with the development and commercialization of BCA101 and any other approved product;
- the size and growth potential of the markets for BCA101 and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of BCA101;
- regulatory developments in the United States, Canada, European Union and other foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or BCA101 with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- our use of the proceeds from this offering;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those listed under the caption “*Risk Factors*.”

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “*Risk Factors*” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$ _____ million, or \$ _____ million if the underwriters exercise their option to purchase additional shares of our common stock in full, assuming an initial public offering price of \$ _____ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by \$ _____ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each 1.0 million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by \$ _____ million, assuming no change in the assumed initial public offering price of \$ _____ per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for the following:

- approximately \$ _____ million to advance the development of BCA101 in head and neck squamous cell carcinoma, and fund our pivotal Phase 2/3 trial;
- approximately \$ _____ million to fund expansion of BCA101 in additional head and neck squamous cell carcinoma patient populations;
- approximately \$ _____ million to advance the development of BCA101 in additional solid tumors, such as colorectal cancer and other squamous cell carcinomas including the initiation of clinical trials, clinical research outsourcing and drug manufacturing; and
- the remainder for working capital and other general corporate purposes.

Based on our current plans, we believe that our existing cash and cash equivalents and together with the net proceeds from this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through _____. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external source of funds.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or technologies to continue to build our pipeline, research and development capabilities and our intellectual property position, although we currently have no agreements, commitments or understandings with respect to any such transaction.

Due to the many inherent uncertainties in the development of our product candidate, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of our ongoing clinical studies or clinical studies we may commence in the future, the timing of

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regulatory submissions, any strategic alliances that we may enter into with third parties for our product candidate or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2023:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all 306,985,117 outstanding shares of our redeemable convertible preferred stock in the aggregate into the equivalent number of shares of common stock prior to the completion of this offering and (ii) the filing and effectiveness of our fifth amended and restated certificate of incorporation prior to the completion of this offering, in each case as if such events had occurred on December 31, 2023; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our financial statements and the related notes appearing at the end of this prospectus and in the section titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*”.

| (in thousands, except share and per share amounts) | As of December 31, 2023 | | |
|---|--------------------------------|-------------------|--|
| | Actual | Pro forma | Pro forma as adjusted⁽¹⁾ |
| Cash and cash equivalents | \$ 230,440 | \$ 230,440 | \$ |
| Series Seed redeemable convertible preferred stock, \$0.0001 par value; 81,790,144 shares authorized; 81,790,144 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 81,525 | — | |
| Series B redeemable convertible preferred stock, \$0.0001 par value; 105,595,101 shares authorized; 105,595,101 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 121,148 | — | |
| Series C redeemable convertible preferred stock, \$0.0001 par value; 119,599,872 shares authorized; 119,599,872 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 164,064 | — | |
| Stockholders’ equity (deficit): | | | |
| Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; _____ shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted | — | — | |
| Common stock, \$0.0001 par value; 365,000,000 shares authorized, 6,580,404 shares issued and 5,919,414 shares outstanding, actual; _____ shares authorized, 313,533,421 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted | 2 | 33 | |
| Additional paid-in capital | 4,250 | 371,496 | |
| Accumulated deficit | (153,021) | (153,021) | |
| Total stockholders’ (deficit) equity | (148,769) | 218,508 | |
| Total capitalization | \$ 218,508 | \$ 218,508 | \$ |

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents total stockholders' equity and total capitalization by \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents total stockholders' equity and total capitalization by \$ _____ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock in the table above on a pro forma and pro forma as-adjusted basis is based on 313,533,421 shares of our common stock (which includes 436,290 shares of unvested restricted common stock and 192,600 shares of unvested early exercise stock options) outstanding as of December 31, 2023, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 306,985,117 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 44,837,663 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2023 under our 2019 Plan at a weighted average exercise price of \$0.49 per share;
- 2,755,000 shares of common stock issuable upon the exercise of stock options granted after December 31, 2023 pursuant to our 2019 Plan at a weighted average exercise price of \$0.68 per share;
- 4,239,537 shares of common stock reserved for future issuance as of December 31, 2023 under the 2019 Plan, which will cease to be available for issuance at the time that our 2024 Plan becomes effective;
- _____ shares of common stock reserved for future issuance under our ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; and
- _____ shares of our common stock that will become available for future issuance under our 2024 Plan, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2024 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled, or withheld.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Dilution in pro forma as adjusted net tangible book value represents the difference between the assumed initial price to the public per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of December 31, 2023 was a deficit of \$(148.8) million, or \$(22.7) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying values of our redeemable convertible preferred stock, which is not included within stockholders' deficit. Our historical net tangible book value per share represents historical net tangible book deficit divided by the number of shares of our common stock outstanding as December 31, 2023, including 436,290 shares of unvested restricted stock awards and 192,600 shares of unvested early exercise stock options (which are not considered outstanding for accounting purposes).

Our pro forma net tangible book value as of December 31, 2023 was \$218.5 million, or \$0.7 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all 306,985,117 outstanding shares of our redeemable convertible preferred stock in the aggregate into the equivalent number of shares of common stock immediately prior to the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2023, after giving effect to the pro forma adjustment described above.

After giving further effect to our issuance and sale of _____ shares of our common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2023 would have been \$ _____ million, or \$ _____ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value per share of \$ _____ to our existing stockholders and immediate dilution of \$ _____ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

| | |
|--|----------|
| Assumed initial public offering price per share | \$ |
| Historical net tangible book deficit per share as of December 31, 2023 | \$(22.7) |
| Increase per share attributable to the pro forma adjustments described above | |
| Pro forma net tangible book value per share as of December 31, 2023 attributable to the conversion of redeemable convertible preferred stock | 0.7 |
| Increase in pro forma net tangible book value per share attributable to new investors participating in this offering | |
| Pro forma as adjusted net tangible book value per share after this offering | |
| Dilution per share to new investors purchasing common stock in this offering | \$ |

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the

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assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by \$ _____ and dilution per share to new investors purchasing common stock in this offering by \$ _____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by \$ _____ and decrease dilution per share to new investors purchasing common stock in this offering by \$ _____, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by \$ _____ and increase dilution per share to new investors purchasing common stock in this offering by \$ _____, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to _____ additional shares of our common stock in full, our pro forma as adjusted net tangible book value per share after this offering would be \$ _____ per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$ _____ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$ _____ per share to new investors purchasing common stock in this offering, based on the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$ _____ per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

| | Shares Purchased | | Total Consideration | | Average Price Per Share |
|-----------------------|------------------|------------|---------------------|------------|-------------------------|
| | Number | Percentage | Amount | Percentage | Share |
| Existing stockholders | | % | \$ | % | \$ |
| New investors | | | | | |
| Total | | 100% | \$ | 100% | |

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares of our common stock is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to _____ % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to _____ % of the total number of shares of our common stock outstanding after this offering.

The discussion and tables above on a pro forma and pro forma as-adjusted basis are based on 313,533,421 shares of our common stock (which includes 436,290 shares of unvested restricted common stock and 192,600 shares of unvested early exercise stock options) outstanding as of December 31, 2023, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into the aggregate of 306,985,117 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 44,837,663 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2023 under our 2019 Plan at a weighted average exercise price of \$0.49 per share;

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- 2,755,000 shares of common stock issuable upon the exercise of stock options granted after December 31, 2023 pursuant to our 2019 Plan, at a weighted average exercise price of \$0.68 per share;
- 4,239,537 shares of common stock reserved for future issuance as of December 31, 2023 under the 2019 Plan, which will cease to be available for issuance at the time that our 2024 Plan becomes effective;
- shares of common stock reserved for future issuance under our ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; and
- shares of our common stock that will become available for future issuance under our 2024 Plan, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2024 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled, or withheld.

To the extent that new stock options are issued or any outstanding options are exercised, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022, and related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Our lead program BCA101 is a bifunctional antibody that combines two clinically validated targets, an epidermal growth factor receptor, or EGFR, directed monoclonal antibody with a domain that binds to human transforming growth factor beta, or TGF- β . Through this dual-targeting mechanism, BCA101 has the potential to exert potent anti-tumor activity by simultaneously blocking both cancer cell-intrinsic EGFR survival and proliferation, as well as the immunosuppressive TGF- β signaling within the tumor microenvironment, or TME. BCA101 directs the TGF- β inhibitor into the immediate TME through the binding of EGFR on tumor cells, which we believe will lead to durable responses and an increase in overall survival, or OS, while reducing the adverse effects typically associated with systemic TGF- β inhibition. BCA101 is initially being developed in head and neck squamous cell carcinoma, or HNSCC, where there remains a significant unmet need. We intend to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in recurrent/metastatic, HNSCC excluding patients with HPV-positive oropharyngeal squamous cell carcinoma, or OPSCC, in . Based on discussions with the U.S. Food and Drug Administration, or FDA, we believe that this trial may enable us to seek accelerated approval for BCA101 in combination with pembrolizumab.

Since our inception in December 2018, we have not generated any revenue from product sales or other sources and have incurred significant operating losses and negative cash flows from our operations. Our primary uses of cash to date have been conducting research and development, advancing development of BCA101, raising capital, building infrastructure, developing intellectual property, hiring personnel and providing general and administrative support for these operations. To date, we have funded our operations primarily through private placements of our redeemable convertible preferred stock, sale of common stock and through debt financing. As of December 31, 2023, we had raised aggregate proceeds of \$353.2 million and had cash and cash equivalents of \$230.4 million.

We have incurred operating losses in each year since our inception. Our net losses were \$52.0 million and \$37.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$153.0 million. We expect our expenses and operating losses will increase substantially as we:

- conduct our current and future clinical trials;
- continue our research and development activities;
- utilize third parties to manufacture our product candidate and related raw materials or, should we decide to do so, build and maintain a commercial-scale current good manufacturing practice, or cGMP, manufacturing facility;

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- hire additional research and development, clinical and commercial, and operational personnel;
- add quality control, quality assurance, legal, compliance, and other groups to support our operations;
- maintain, expand, enforce, defend and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- seek regulatory approvals for BCA101 or any future product candidates for which we successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize BCA101 or any future product candidates for which we may obtain marketing approval;
- make any payments due under our license agreements and any potential milestones, royalties or other payments due under any future in-license or collaboration agreements; and
- incur additional costs associated with being a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities.

Based upon our current operating plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations into . Without additional funding, we believe that we will have sufficient funds to meet our obligations within the next twelve months from the date of issuance of our consolidated financial statements. See the section titled “*Use of Proceeds*.” We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for BCA101 or future product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for BCA101 or any of our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our product candidate, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. See the section titled “*Liquidity and Capital Resources*” below. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidate that we would otherwise prefer to develop and market ourselves.

Components of Results of Operations

Revenue

We currently have no products approved for sale, and we have not generated any revenue to date. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidate, as well as product sales from any approved product, which approval we do not expect to occur for at least the next several years, if ever. Our ability to generate product revenue will depend on the successful development and eventual commercialization of BCA101 and any future product candidates we pursue. If we fail to complete clinical development of or to obtain regulatory approval for BCA101 or any future product candidates, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating Expenses

Research and Development (including Research and Development—Related Party)

Research and development expenses (including related party research and development) have primarily consisted of external and internal costs associated with our research and development activities, including the development of our bifunctional BCA101 antibody therapies to treat solid tumors, and the clinical development of our product candidate. Our research and development expenses include:

- external expenses, including expenses incurred under arrangements with third parties, such as sponsored research agreements, consultants and our scientific advisors;
- the cost to obtain licenses to intellectual property;
- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- costs for laboratory supplies, research materials and reagents; and
- the cost of developing and validating our manufacturing process for use in our future clinical trials;

Most of our research and development expenses have been related to the development of BCA101. We have not reported program costs since our inception because we have not historically tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing our product candidate.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, related parties and third-party service providers.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue with the development of BCA101 and any other product candidates we may determine to pursue. Due to the inherently unpredictable nature of pre-clinical and clinical development, we cannot determine with certainty the timing of the initiation, duration or costs of future clinical trials and pre-clinical studies of product candidates. The timelines and costs associated with research and development activities are uncertain and can vary significantly for any product candidate we pursue, and development programs are inherently unpredictable nature of clinical development. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each current program on an ongoing basis in response to clinical results, regulatory developments, and ongoing assessments as to each program's commercial potential.

Research and development activities are central to our business model. Therapeutic candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we expect to (i) advance BCA101 into late-stage clinical trials, (ii) develop BCA101 for other potential indications and (iii) expand our manufacturing efforts.

Our future development costs may vary significantly based on various factors such as timely and successful completion of clinical trials, positive results from our future clinical trials, receipt of marketing approvals from applicable regulatory authorities, establishment of arrangements with third parties, intellectual property updates, and continued acceptable safety, tolerability and efficacy profile of any product candidates that we may develop following approval. Any changes in the outcome of any of these variables with respect to the development of our therapeutic candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these therapeutic candidates. For example, if the FDA or another

regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time to complete clinical development of that therapeutic candidate. We may never obtain regulatory approval for any of our therapeutic candidates, and, even if we do, drug commercialization takes several years and millions of dollars in development costs.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation charges for those individuals in executive, legal, finance, human resources, facility operations, and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for auditing, accounting, tax and consulting services, office and information technology costs, insurance costs, and facilities, depreciation and other general and administrative expenses, which include rent and maintenance of facilities and utilities.

We anticipate that our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities. We also anticipate increased expenses related to audit, accounting, legal, regulatory, and tax-related services associated with maintaining compliance with our Nasdaq and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Other (Expense) Income

Interest expense—related party

Interest expense—related party consists of interest incurred at the stated rate on an unsecured loan agreement with Biocon Pharma. See the section titled “*Certain Relationships and Related Party Transactions—Biocon Loan Agreement*”.

Interest income

Interest income consists primarily of interest income earned on cash and cash equivalents. We expect our interest income will increase as we invest the cash received from our sales of Series B and C redeemable convertible preferred stock in 2023 and the net proceeds from this offering.

Change in fair value of Series B convertible preferred stock tranche rights liability

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the consolidated financial statements. We present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the Series B convertible preferred stock tranche rights liability were recognized in the consolidated statements of operations. See the section titled “*Series B Tranche Rights*” below for additional details.

Income Taxes

The Company’s provision for income taxes is not material for the years ended December 31, 2023 and 2022.

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

| | Year ended December 31, | | Change |
|---|-------------------------|--------------------|--------------------|
| | 2023 | 2022 | |
| Operating expenses | | | |
| Research and development—related party | \$ 9,244 | \$ 12,936 | \$ (3,692) |
| Research and development | 21,373 | 18,376 | 2,997 |
| General and administrative | 9,272 | 6,344 | 2,928 |
| Total operating expenses | <u>39,889</u> | <u>37,656</u> | <u>2,233</u> |
| Loss from operations | (39,889) | (37,656) | (2,233) |
| Other (expenses) income | | | |
| Interest expense—related party | — | (112) | 112 |
| Interest income | 1,314 | 4 | 1,310 |
| Change in fair value of Series B preferred stock tranche rights liability | (13,405) | — | (13,405) |
| Other expense, net | — | (80) | 80 |
| Total other expense | <u>(12,091)</u> | <u>(188)</u> | <u>(11,903)</u> |
| Net loss before income taxes | (51,980) | (37,844) | (14,136) |
| Income tax expense | (5) | (1) | (4) |
| Net loss | <u>\$ (51,985)</u> | <u>\$ (37,845)</u> | <u>\$ (14,140)</u> |

Research and Development Expenses (including Research and Development—Related Party)

Research and development expenses decreased by \$0.7 million from \$31.3 million for the year ended December 31, 2022, to \$30.6 million for the year ended December 31, 2023. The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022 (in thousands):

| | Year ended December 31, | | Change |
|--|-------------------------|------------------|-----------------|
| | 2023 | 2022 | |
| Research | \$ 1,387 | \$ 7,079 | \$ (5,692) |
| Manufacturing and process development | 11,835 | 13,323 | (1,488) |
| Clinical operations and development | 13,495 | 8,067 | 5,428 |
| Research and development personnel cost (including stock based compensation) | 3,900 | 2,843 | 1,057 |
| Total research and development expenses | <u>\$ 30,617</u> | <u>\$ 31,312</u> | <u>\$ (695)</u> |

The decrease in research and development expenses for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to:

- approximately \$5.7 million in decreased research expenses driven by pausing of preclinical programs and drug discovery expenses; and
- approximately \$1.5 million in decreased manufacturing cost driven by the timing of manufacturing of drug substance.

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These decreases were partially offset by the following:

- approximately \$5.4 million in increased clinical operations and development expenses driven by continued patient enrollment of our ongoing Phase 1/1b trial; and
- approximately \$1.1 million in increased personnel related costs, including stock-based compensation, primarily driven by an increase in the size of our workforce to support clinical development, manufacturing and research and increased professional service expenses as we continue to build out our clinical operations and development functions.

General and Administrative Expenses

General and administrative expenses increased by \$2.9 million from \$6.3 million for the year ended December 31, 2022, to \$9.3 million for the year ended December 31, 2023. The following table summarizes our general and administrative expenses for the years ended December 31, 2023 and 2022 (in thousands):

| | Year ended December 31, | | Change |
|---|-------------------------|-----------------|----------------|
| | 2023 | 2022 | |
| General and administrative personnel costs (including stock-based compensation) | \$ 5,820 | \$ 3,800 | \$2,020 |
| Professional fees | 2,061 | 1,639 | 422 |
| Facility costs, IT, office expense and other | 1,391 | 905 | 486 |
| Total general and administrative expenses | <u>\$ 9,272</u> | <u>\$ 6,344</u> | <u>\$2,928</u> |

The increase in general and administrative expenses for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to:

- approximately \$2.0 million in increased personnel related costs, including stock-based compensation, primarily driven by an increase in the size of our workforce;
- approximately \$0.4 million in increased professional service expenses, including legal, accounting and other expenses as we continue to build out our general and administrative functions to support advancing our clinical studies; and
- approximately \$0.5 million in increased information technology expenses and related miscellaneous expenses.

Other (Expense) Income

Interest expense—related party

Interest expense—related party for the years ended December 31, 2023, and 2022 was \$0 and \$0.1 million, respectively. The decrease was due to conversion of an unsecured loan and accrued interest into convertible preferred stock of the Company. See the section titled “*Certain Relationships and Related Party Transactions—Biocon Loan Agreement*”.

Interest income

Interest income for the years ended December 31, 2023 and 2022 was \$1.3 million and \$0, respectively. The increase was primarily due to an increase in cash equivalents.

Change in fair value of Series B convertible preferred stock tranche rights liability

Change in fair value of Series B convertible preferred stock tranche rights liability for the years ended December 31, 2023 and 2022 was \$13.4 million and \$0, respectively. The loss was primarily due to the increase in fair value of the Series B convertible preferred shares sold in connection with tranching milestone closings.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in December 2018, we have not generated any revenue from any sources and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of BCA101 or any future product candidates we elect to pursue. Further, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. From our inception in December 2018 through December 31, 2023, we have received aggregate proceeds of \$353.2 million from the sale of our redeemable convertible preferred stock in private placements, sale of common stock and debt financing.

Future Funding Requirements

As of December 31, 2023, we had cash and cash equivalents of \$230.4 million. Based upon our current operating plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations into . However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Additionally, the process of testing our product candidate in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. We will need to raise substantial additional capital in the future.

Our future capital requirements will depend on many factors, including but not limited to:

- the type, number, scope, progress, expansions, results, costs, and timing of, clinical trials of BCA101 and future product candidates;
- the costs and timing of manufacturing for BCA101 and any future product candidates and commercial manufacturing thereof;
- the costs, timing, and outcome of regulatory review of BCA101 and any future product candidates;
- the terms and timing of establishing and maintaining licenses and other similar arrangements;
- the legal costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights (including intellectual property obtained through license agreements);
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- the costs associated with hiring additional personnel and consultants as our clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if BCA101 or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenue to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, potentially including collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific

actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or current or future product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our current or future product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

Comparison of the Years Ended December 31, 2023 and 2022

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2023 and 2022 (in thousands):

| | Year ended December 31, | |
|--|-------------------------|-----------------|
| | 2023 | 2022 |
| Cash used in operating activities | \$ (45,628) | \$ (32,076) |
| Cash used in investing activities | (586) | (192) |
| Cash provided by financing activities | 272,496 | 31,695 |
| Net increase (decrease) in cash and cash equivalents | <u>\$ 226,282</u> | <u>\$ (573)</u> |

Operating Activities

For the year ended December 31, 2023, net cash used in operating activities was \$45.6 million resulting from our net loss of \$52.0 million and net changes in our operating assets and liabilities of \$9.6 million partially offset by non-cash charges of \$16.0 million. Net cash used by changes in our operating assets and liabilities were primarily due to an increase in prepaid expenses and other assets of \$0.9 million and by decreases in accounts payable and accrued expenses of \$8.7 million.

For the year ended December 31, 2022, net cash used in operating activities was \$32.1 million resulting from our net loss of \$37.8 million partially offset by non-cash charges of \$0.8 million and changes in our operating assets and liabilities of \$4.9 million. Net cash provided by changes in our operating assets and liabilities were primarily due to increases in accounts payable and accrued expenses of \$5.9 million partially offset by an increase in prepaid expenses and other assets of \$0.9 million.

Investing Activities

Net cash used in investing activities was \$0.6 million during the year ended December 31, 2023 as compared to \$0.2 million during the year ended December 31, 2022. The increase in net cash used in investing activities was due to an increase in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was \$272.5 million during the year ended December 31, 2023 as compared to \$31.7 million during the year ended December 31, 2022. The increase in net cash provided by financing activities was primarily due to the net proceeds of \$272.3 million raised from the sale of our convertible preferred stock and Series B tranche rights in connection with Series B and Series C convertible preferred stock financings.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2023 (in thousands):

| | Payment Due by Period | | | |
|-----------------------------|-----------------------|------------------|-----------|-----------|
| | Total | Less than 1 Year | 1-3 Years | 4-5 Years |
| Operating lease commitments | \$720 | \$ 329 | \$ 335 | \$ 56 |
| Total | \$720 | \$ 329 | \$ 335 | \$ 56 |

We enter into contracts in the normal course of business with contract research organizations for clinical trials, with contract manufacturing organizations, or CMOs, for clinical supplies manufacturing and with other vendors for supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancellable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancellable obligations under these agreements as of December 31, 2023 and 2022.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 titled "Summary of Significant Accounting Policies" to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

We are required to estimate our expenses resulting from obligations under contracts with vendors and consultants, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the clinical studies as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from our estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Series B Tranche Rights

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the consolidated financial statements. We present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value is recognized in the consolidated statements of operations.

The Company's Series B convertible preferred stock financing included tranche rights, or the Series B Tranche Rights, to purchasers who participated in the initial Series B convertible preferred stock issuance. The Series B Tranche Rights were determined to be a "freestanding financial instrument" as defined in the ASC Master Glossary as they were legally detachable and separately exercisable. Management assessed the freestanding financial instrument under ASC 480, Distinguishing Liabilities from Equity, and determined that such rights should be accounted for as a liability at fair value given they imposed a contingent obligation on the Company to issue additional Series B convertible preferred shares that would be contingently redeemable. The Series B Tranche Rights were revalued at each reporting period until settlement, with changes in the fair value recorded in the consolidated statements of operations.

Common Stock Valuation

Due to the absence of an active market for our common stock, we utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: *Valuation of Privately-Held Company Equity Securities Issued as Compensation* to estimate the fair value of our common stock. In determining the exercise prices for options granted, we considered the fair value of the common stock as of the grant date. The fair value of our common stock was determined by our board of directors using a variety of factors, including: valuations of our common stock performed with the assistance of independent third-party valuation specialists; our stage of development and business strategy, including the status of research and development efforts of our product candidate, and the material risks related to our business and industry; our business conditions and projections; our results of operations and financial position, including our levels of available capital resources; the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies; the lack of marketability of our common stock as a private company; the prices of our preferred stock sold to third party investors, and the rights, preferences and privileges of our preferred stock relative to those of our common stock; the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale given prevailing market conditions; trends and developments in our industry; the hiring of key personnel and the experience of management; and external market conditions affecting the life sciences and biotechnology industry sectors. Significant changes to the key assumptions underlying the factors used could result in different fair values of our common stock at each valuation date.

Valuation Methodologies

Our common stock valuations were prepared in accordance with the guidelines in the AICPA Practice Aid, which prescribes several valuation approaches for determining the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its capital structure and specifically the common stock.

Our common stock valuations were prepared using the back-solve method to calculate the total equity value and the option-pricing method, or OPM, to allocate the total equity value. The back-solve method derives the

implied equity value for one type of equity security from a contemporaneous transaction involving another type of security. We used the back-solve method to calculate the total equity value of our company as we had recently completed redeemable convertible preferred stock financings that should be considered in estimating the fair value of our equity per the AICPA Practice Aid.

The OPM method allows for the allocation of a company's equity value among the various equity capital owners (preferred and common shareholders). The OPM uses the preferred shareholders' liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option awards using the Black-Scholes option pricing model and recognize forfeitures as they occur.

The Black-Scholes option pricing model requires the use of subjective assumptions, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield, and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require judgment to develop. See Note 11 titled "*Stock-based Compensation*" to our consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted for the years ended December 31, 2023, and 2022, respectively. Stock-based compensation totaled \$1.9 million and \$0.8 million for the years ended December 31, 2023, and 2022, respectively.

As of December 31, 2023, the unrecognized stock-based compensation expense related to stock options was \$14.9 million which is expected to be recognized as expense over a weighted-average period of approximately 3.58 years. The intrinsic value of all outstanding stock options as of December 31, 2023, was approximately \$ million, based on the assumed public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, of which approximately \$ million related to vested options and approximately \$ million related to unvested options.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of December 31, 2023, we had \$230.4 million in cash and cash equivalents, which consisted of cash and money market funds. Our cash and cash equivalents are primarily maintained in accounts with multiple financial institutions in the United States. At times, we may maintain cash and cash equivalent balances in excess of Federal Deposit Insurance Corporation limits. We do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Foreign Currency Exchange Risk

We are exposed to foreign exchange rate risk. Our headquarters is located in the United States, where the majority of our general and administrative expenses and research and development costs are incurred in U.S. dollars. While we are subject to fluctuations in foreign currency rates in connection with these arrangements, to date, these fluctuations have not been significant. Based on our expected volumes with these vendors and employees in fiscal year 2023, a movement of 10% in the exchange rates would not have a material effect on our results of operations or financial condition.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and (v) an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our shares of common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our shares of common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 titled “*Summary of Significant Accounting Policies*” to our consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Our lead program BCA101 is a bifunctional antibody that combines two clinically validated targets, an epidermal growth factor receptor, or EGFR, directed monoclonal antibody with a domain that binds to human transforming growth factor beta, or TGF-b. Through this dual-targeting mechanism, BCA101 has the potential to exert potent anti-tumor activity by simultaneously blocking both cancer cell-intrinsic EGFR survival and proliferation, as well as the immunosuppressive TGF-b signaling within the tumor microenvironment, or TME. BCA101 directs the TGF-b inhibitor into the immediate TME through the binding of EGFR on tumor cells, which we believe will lead to durable responses and an increase in overall survival, or OS, while reducing the adverse effects typically associated with systemic TGF-b inhibition. BCA101 is initially being developed in head and neck squamous cell carcinoma, or HNSCC, where there remains a significant unmet need. We intend to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in recurrent/metastatic, or R/M, HNSCC excluding patients associated with human papillomavirus infection, or HPV-positive patients, with oropharyngeal squamous cell carcinoma, or OPSCC, in . Based on discussions with the U.S. Food and Drug Administration, or FDA, we believe that this trial may enable us to seek accelerated approval for BCA101 in combination with pembrolizumab.

We are conducting an ongoing Phase 1/1b trial of BCA101 which, includes a cohort of HNSCC patients who were treatment-naïve in the R/M setting. In this cohort, treatment with BCA101 in combination with pembrolizumab resulted in a 54% (21/39) overall response rate, or ORR, in the efficacy evaluable population, and a 64% (18/28) ORR in patients not associated with human papillomavirus infection, or HPV-negative patients. These data reflect a substantial increase over the 19% historical response rate observed in a Phase 3 trial with pembrolizumab monotherapy, the current standard of care in R/M HNSCC. Furthermore, the combination therapy demonstrated an 18% (5/28) complete response rate, or CR rate, and a median progression-free survival, or mPFS, of 9.8 months in HPV-negative patients. With at least 12 months of follow-up, median OS has not yet been reached, and we expect to announce updated interim Phase 1/1b data at future medical meetings. Based on the clinical data generated to date, we believe that BCA101 in combination with pembrolizumab has the potential to become a first-line chemotherapy-free standard of care therapy in HPV-negative R/M HNSCC.

We also believe BCA101 has the potential to provide meaningful clinical benefit in other solid tumors where there is a strong biologic rationale for the dual inhibition of both EGFR and TGF-b, such as colorectal cancer and other squamous cell carcinomas which typically overexpress EGFR and TGF-b pathways. We have demonstrated preliminary activity of BCA101 in combination with pembrolizumab or as a monotherapy across several squamous cell carcinomas, including cutaneous squamous cell carcinoma, or CSCC. Within our Phase 1/1b dose expansion cohorts, we have observed to date a preliminary 42% (5/12) ORR with BCA101 monotherapy in relapsed and/or refractory CSCC patients.

We have built a platform designed to facilitate the development of bifunctional therapies that precisely target the tumor and deliver a tumor-modulating payload to the tumor site. This dual-targeting approach both enhances drug exposure within the TME and limits systemic toxicity. This approach was deployed in the development of BCA101, where we believe the bifunctional design can improve upon the therapeutic profile of immunotherapies and targeted therapies by addressing resistance mechanisms and limiting off-target toxicity, therefore, enhancing the treatment effect and tolerability for targeted patient populations with cancer.

EGFR is the primary member of a larger family of cell-surface growth factor receptors harboring intrinsic tyrosine kinase function. EGFR is involved in many tumor-promoting pathways. Its overexpression has been linked to multiple squamous cell cancers, including HNSCC, where EGFR expression has been shown to be greater than 90%. EGFR has been a long-standing focus for cancer drug development due to the correlation between EGFR expression, poor prognosis and resistance to therapy. Cetuximab is an EGFR-directed

monoclonal antibody approved for HNSCC and colorectal cancer that drives anti-tumor responses by inhibiting EGFR signaling and through antibody-dependent cell-mediated cytotoxicity, or ADCC. However, acquired resistance mechanisms to cetuximab can prevent durable responses. We believe that there is a significant market opportunity for EGFR targeted therapies with improved efficacy, durability and OS compared to cetuximab.

TGF- β is a cytokine that controls a range of biological functions and is widely understood to play a critical role in cancer. TGF- β perpetuates tumor survival by promoting tumor cell proliferation, migration, invasion and metastasis. TGF- β also serves as an immunosuppressant, inhibiting both natural killer, or NK, cells and cytotoxic T cells. The inhibition of TGF- β has been demonstrated to improve anti-tumor responses *in vivo*. However, these findings have not been translated into substantial improvements in clinical efficacy, which we believe may be due to the inability to sufficiently inhibit TGF- β directly within the TME. Increased TGF- β expression within the TME contributes to an immune-excluded environment.

BCA101 was designed to leverage the well-established biologies of both the clinically validated anti-EGFR antibody cetuximab and a TGF- β binding domain to deliver a potent anti-tumor therapy, sequestering TGF- β directly to EGFR-expressing tumors with the goal of limiting off-target toxicity. We have shown both *in vitro* and *in vivo* that BCA101 performs as expected, by binding to both targets, localizing to the tumor, inhibiting tumor growth and suppressing TGF- β levels within tumors.

HNSCC is one of the most common cancers in the United States and globally with a rising incidence anticipated to reach one million new global cases annually by 2030. Ten percent of HNSCC patients are diagnosed with metastatic disease and up to 30% develop a recurrence or metastases over time after initial treatment for advanced HNSCC. Median OS for patients with R/M HNSCC is only 12 months. Most cases of HNSCC are believed to arise from mutations that accumulate due to carcinogenic exposure, such as tobacco smoke, or by HPV. Approximately 80% of patients with R/M HNSCC are HPV-negative, a status associated with a worse prognosis. Pembrolizumab monotherapy is the standard of care for R/M HNSCC patients who have evidence of PD-L1 expressing tumors is pembrolizumab monotherapy. The KEYNOTE-048 Phase 3 trial of pembrolizumab conducted by Merck & Co. Inc., or Merck & Co, demonstrated an ORR of 19% with a mPFS of 3.2 months in a population of HPV-negative and HPV-positive patients with CPS greater than or equal to one. For patients with a CPS less than one and no PD-L1 expression within their TME, the typical standard of care is the EXTREME regimen, a combination of cetuximab and chemotherapy, which has low response rates and survival, as well as a difficult tolerability profile.

We believe the poor prognoses in HPV-negative R/M HNSCC and the low ORR associated with available therapies may be attributed to the elevated levels of TGF- β observed in these patients. It has been shown in translational studies that EGFR inhibition leads to further increases in TGF- β levels which result in the development of resistance to EGFR-targeted therapeutics. We believe blocking TGF- β has the potential to prevent resistance and improve the anti-tumor activity of anti-EGFR therapies, leading to more durable responses and an increase in OS. Similarly, inhibiting TGF- β may reduce the fibrosis and immune-exclusion within the TME that could be responsible for the low efficacy seen with checkpoint inhibitors in these immunosuppressive, or “cold” tumors. We believe promoting immune activation via TGF- β blockade may translate to significant increases in anti-tumor efficacy, particularly in the depth and durability of responses in combination with anti-PD1 therapies.

We are working to bring BCA101, a potentially transformative therapy, to patients as quickly as possible. As a result of our discussions with the FDA, we believe that BCA101 has a path to accelerated approval using an ORR-based interim endpoint with confirmatory approval based on an OS endpoint. We have designed a double-blind, placebo-controlled Phase 2/3 trial in R/M HNSCC patients, excluding patients with HPV-positive OPSCC, which we believe is sufficiently powered to achieve results that may lead to accelerated approval. This trial will enroll approximately 750 patients with a PD-L1 CPS greater than or equal to one, and who have not received systemic therapy in the R/M setting. We intend to conduct an interim analysis to determine if the ORR is sufficient to seek accelerated approval and will continue the trial with the goal of demonstrating a statistically

significant improvement in OS. We anticipate initiating this trial in [redacted] and project that the ORR interim analysis may occur in [redacted].

Our Strengths

Our company was founded with the goal of bringing transformative bifunctional therapies to patients with solid tumors. To advance that goal, we are focusing our efforts on the development of our lead program, BCA101, for the treatment of R/M HNSCC, where there remains a significant unmet need. We believe the following competitive strengths will allow us to successfully develop, commercialize and maximize the impact of BCA101:

- **Validated dual-targeting mechanism of action with potential to exert potent and durable anti-tumor activity.**

BCA101 is a bifunctional antibody designed to simultaneously block both cancer cell-intrinsic EGFR survival and proliferation, as well as the well-understood immunosuppressive TGF- β signaling within the TME. BCA101 leverages the established biology of the clinically validated anti-EGFR antibody cetuximab. However, BCA101 is differentiated from existing therapies through the targeting of TGF- β , which localizes the ligand to EGFR expressing tumor cells, potentially increasing its activity at the tumor site and limiting systemic toxicity. Importantly, TGF- β inhibition synergizes with EGFR, which we believe will prevent resistance to treatment and lead to more durable responses.

- **Clinical data generated to date representing meaningful improvements over standard of care.**

We have generated compelling interim clinical data for BCA101 in a Phase 1/1b trial of R/M HNSCC patients. In this trial, treatment with BCA101 in combination with pembrolizumab led to a 64% ORR (18/28) in HPV-negative patients, which is a substantial increase over the 19% historical response rate reported with pembrolizumab monotherapy in R/M HNSCC in the KEYNOTE-048 Phase 3 trial conducted by Merck & Co that included HPV-negative and HPV-positive patients. The combination also demonstrated an 18% (5/28) CR rate and mPFS of 9.8 months in the same patient population. With at least 12 months of follow-up, median OS has not yet been reached, and we expect to announce updated interim Phase 1/1b data at future medical meetings. We believe these encouraging initial clinical data demonstrate the potential of BCA101, administered in combination with pembrolizumab, to become a chemotherapy-free, first-line therapy for HPV-negative R/M HNSCC patients.

- **Potential to address significant unmet need in HPV-negative R/M HNSCC with clear development pathway.**

HNSCC is one of the most common cancers, accounting for approximately 4% of all cancers in the United States. An estimated 80% of R/M HNSCC cases are HPV-negative, a status associated with significantly worse outcomes compared to HPV-positive patients. We are prioritizing our initial development efforts in HPV-negative R/M HNSCC given the significant unmet need for durable therapies in this patient population. We also believe that BCA101 will be most effective in this patient subset given the (1) high expression of EGFR, (2) elevated levels of TGF- β and (3) current preclinical and clinical data, including from our own Phase 1/1b study, supporting increased activity within HPV-negative patients. We believe our deliberate patient selection strategy provides the best opportunity to demonstrate the potential of BCA101 as a first-line therapy. We plan to initiate a pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in HPV-negative R/M HNSCC in [redacted]. Based on discussions with the FDA, we believe that this trial may enable an accelerated approval pathway for BCA101.

- **Potential to expand the clinical development of BCA101 in additional patient populations within HNSCC and other solid tumors of squamous cell origin.**

Beyond our initial development plans, we believe there are significant opportunities to expand the clinical development of BCA101 to other populations of HNSCC patients, including for the treatment [redacted].

of locally advanced HPV-negative HNSCC and in the neoadjuvant or adjuvant setting. We also believe BCA101 has the potential to provide meaningful clinical benefit in other EGFR-expressing solid tumors of squamous cell origin, such as colorectal cancer and other squamous cell carcinomas where there is a strong biologic rationale for the dual-inhibition of EGFR and TGF- β pathways. We plan to explore these additional development opportunities to maximize the potential of BCA101 for the treatment of cancer.

- **Strong and experienced team with deep expertise in clinical development.**

We have assembled a seasoned leadership team with extensive and highly relevant experience in the field of oncology drug development. Our organization is comprised of scientific, clinical and business leaders with broad biotechnology expertise. We have a strong track record of study design and execution, exemplified by the rapid enrollment of our Phase 1/1b study. Our mission-driven team will continue to dedicate our collective efforts and resources to our shared goal of delivering transformative therapies to cancer patients.

Our Team

We have assembled a seasoned leadership team of scientific, clinical and business leaders with broad expertise in biotechnology. Claire Mazumdar, Ph.D., M.B.A. our Chief Executive Officer, was previously part of the founding team and led business development and corporate strategy at Rheos Medicines, Inc. Dr. Mazumdar served as a Senior Associate at Third Rock Ventures, LLC, where she focused on company formation and supported business development for their portfolio companies. Ryan Cohlhepp, Pharm.D., our President and Chief Operating Officer, was a founding executive at Rheos Medicines, Inc. and prior to that, was Vice President of Marketing, Operations and Analytics at Takeda Oncology where he was responsible for the company's commercial oncology portfolio in the United States. David Raben, M.D., our Chief Medical Officer, is currently a board-certified radiation oncologist with more than 25 years of biopharma and academic translational oncology experience. His prior roles include Vice President of Global Product Development and Product General Manager of Oncology at Amgen, Inc. and Vice President and Franchise Leader of Clinical Oncology at Genentech, Inc. focused on non-small cell lung cancer, or NSCLC, skin cancer and HNSCC. Ivan Hyep, our Chief Financial Officer, previously served as Head of Finance at MOMA Therapeutics, Inc. and Director of Finance at Third Rock Ventures, LLC after 10 years at Bain Capital, LP. Lara Meisner, J.D., our Chief Legal Officer, previously served as Chief Legal Officer at Viridian Therapeutics, Inc. and in various senior legal roles at Astria Therapeutics, Inc. and Verastem, Inc.

Our team is supported by a group of investors who have shared our vision and commitment to developing transformative bifunctional therapies for patients with solid tumors. Since our inception, we have raised \$353 million, including a \$165 million Series C financing in December 2023. Our leading syndicate of investors includes RA Capital Management, Red Tree Venture Capital, F-Prime Capital, Eight Roads Ventures, Omega Funds, Invus and TPG, as well as Biocon Limited, a global biopharmaceutical company and leader in the development of biologics.

The Established Role of EGFR and TGF- β in Squamous Cell Carcinomas and other Solid Tumors

Targeting EGFR in squamous cell carcinomas and other solid tumors

EGFR is a cell-surface tyrosine kinase growth factor receptor that is involved in many tumor-promoting pathways. Activation of EGFR pathways leads to cell cycle progression, reduction in cell death, blood vessel formation and a metastatic phenotype. EGFR overexpression has been linked to several cancers of squamous cell origin, including HNSCC, CSCC and colorectal cancer. Several of these cancer types show EGFR expression in tumors to be greater than 50%, with greater than 90% expression in HNSCC. EGFR overexpression in tumors has been shown to correlate with poor prognosis and resistance to therapy. For this reason, the development of therapies targeting EGFR has been a long-standing focus in cancer drug development.

EGFR-directed monoclonal antibodies, such as cetuximab, drive anti-tumor responses both through inhibiting EGFR signaling and through ADCC. ADCC-mediated cell killing occurs when NK cells recognize and bind to antibodies containing an IgG1 Fc domain, which are bound to their respective tumor cell surface antigens. Cetuximab is approved in HNSCC and colorectal cancer, two tumor types where EGFR overexpression is at its highest and has also shown the highest anti-tumor efficacy. The durability of EGFR-targeted therapies has been limited by acquired resistance mechanisms.

Due to its role as a well-validated tumor antigen, EGFR-directed monoclonal antibodies are utilized to deliver anti-tumor payloads directly to the tumor. Currently, there are several EGFR antibody-drug conjugates and bispecific antibodies in development that aim to mitigate the systemic toxicities of chemotherapy-derived drug conjugates by delivering these payloads directly to EGFR-expressing tumors.

The role of TGF- β in cancer progression

TGF- β is a cytokine molecule that functions as a master regulator of immunity and cellular signaling that controls a wide range of biological functions. TGF- β plays multiple essential roles in the body's early development and survival as well as in maintaining health in mature organisms.

In oncogenesis, or the process by which normal, healthy cells turn into cancerous cells, TGF- β both promotes tumor growth and shields tumors from immune surveillance and removal. TGF- β 1 is the most commonly expressed isoform of TGF- β 1 in various human tumor types and is predominantly expressed in cancers of squamous-cell origin, such as HNSCC. Third party studies have demonstrated that TGF- β 1 expression and activation likely contribute to immune escape, which is linked to the primary resistance observed in human tumors against certain cancer therapies. As depicted in Figure 1 below, its immunosuppressive functions are accomplished through a variety of tumor survival mechanisms.

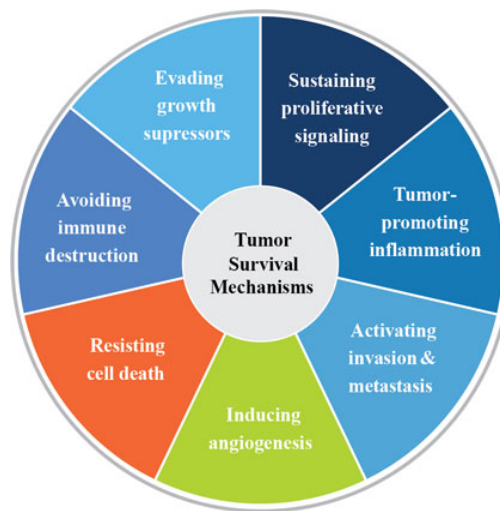


Figure 1. TGF- β promotes tumor survival through multiple mechanisms

TGF- β also serves as a tumor promoter by transforming cells from a more differentiated state to a less differentiated, more primitive state that is no longer dependent on EGFR signaling for proliferation and survival. This shift is known as the epithelial-mesenchymal transition, or EMT, which leads to tumor cell proliferation, migration, invasion and metastasis. Due to its role in cancer progression, we believe the inhibition of TGF- β has

the potential to both limit the tumors' ability to escape EGFR inhibition by switching to an EGFR signaling independent phenotype, as well as restore the immune system's ability to repress tumor growth.

TGF- β as a known EGFR-therapy resistance mechanism

When EGFR signaling is blocked by targeted therapy, such as cetuximab, tumors respond by increasing TGF- β expression within the TME. This results in an increase in tumor cell proliferation and a decrease in the tumor's dependence on EGFR activation, thus making the tumor less sensitive to EGFR inhibition.

In addition to inhibiting direct cell killing by EGFR inhibition, TGF- β protects cells from ADCC both by the activation of survival pathways in tumor cells and through the modulation of the NK cell response. Furthermore, TGF- β both blocks the differentiation of NK cells and reduces NK cell cytotoxicity.

Preclinical studies suggest that targeting TGF- β may lead to improvements in overall efficacy. As depicted in Figure 2 below, experiments published in *Molecular Cancer Therapeutics* in a squamous cell carcinoma cell line xenograft model demonstrate that simultaneous treatment with EGFR and TGF- β blocking antibodies led to complete tumor regression.

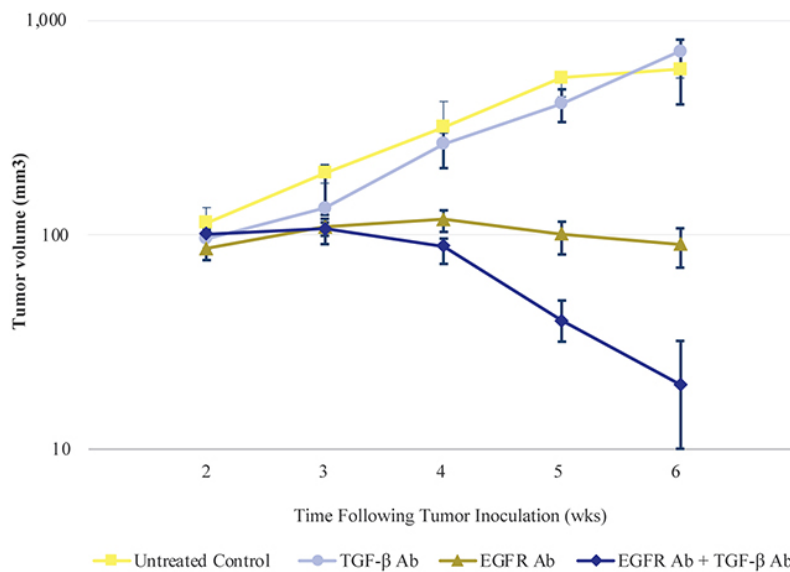


Figure 2. The combination of an anti-EGFR and an anti-TGF- β antibody led to complete regression of a squamous cell carcinoma cell line xenograft tumors

TGF- β as a known checkpoint inhibitor resistance mechanism

The activities of TGF- β extend to the inhibition of cancer immunotherapies known as checkpoint inhibitors. TGF- β inhibits the activation of T cells by PD-1 checkpoint inhibitors and can lead to resistance to anti-PD-1/PD-L1 therapy by promoting immunosuppression and immune exclusion within the TME.

TGF- β promotes immune tolerance of tumors by inducing differentiation of naïve CD4 T cells into regulatory T cells, or Treg cells. Treg cells are components of the immune system that contribute to the

maintenance of immune tolerance. TGF- β can shift the differentiation of naïve CD4 T cells towards Treg cells, thereby leading to immunosuppression. In addition, TGF- β inhibits tumor cell killing by immune cell populations, including CD4 and CD8 T cells and NK cells.

Increased TGF- β expression within the TME contributes to an immune-excluded environment. Specifically, cancer-associated fibroblasts, or CAFs, expressing TGF- β contribute to fibrosis within the TME and result in T-cell exclusion, further limiting the activity of immunotherapy.

As depicted in Figure 3 below, *in vivo* academic studies in an HNSCC xenograft model demonstrated that the effectiveness of anti-PD-1 checkpoint inhibitors was greatly enhanced when administered in combination with anti-TGF- β therapy. Combining an anti-PD-1 antibody with an anti-TGF- β antibody led to significant increases in both CR (top figure) and OS (bottom figure) in this model.

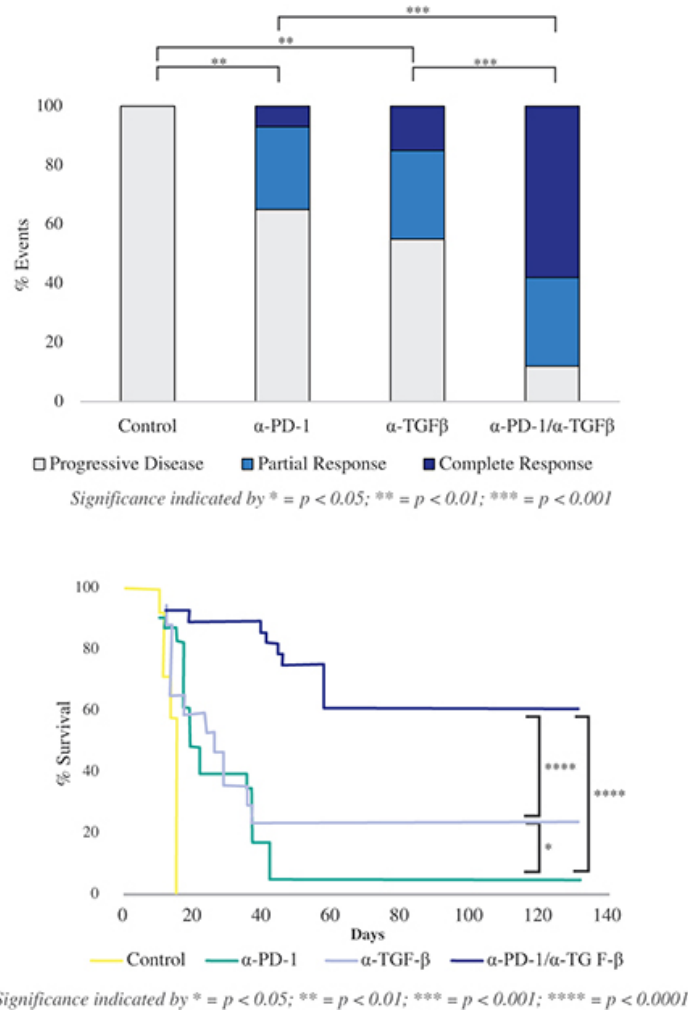


Figure 3. The combination of anti-PD-1 and anti-TGF- β led to improved CR and OS in a SCC xenograft model

Systemic inhibition of TGF- β has had significant limitations in the clinic

The multiple tumor-promoting roles associated with TGF- β have led to multiple attempts to develop systemic anti-TGF- β therapies for the treatment of cancer. These strategies include molecules that inhibit TGF- β activation, molecules that prevent the binding of TGF- β to its cognate receptors, and inhibitors that block intracellular signaling. Despite promising *in vitro* and *in vivo* activity, the outcomes from clinical trials have shown side effects and inadequate improvement in survival.

The first generation of anti-TGF- β therapies had dose-limiting side effects including cardiotoxicities, heart valve lesions, increased risk of bleeding and formation of benign tumors, that were associated with inhibiting all three isoforms of TGF- β . Adverse events associated with systemic inhibition of TGF- β led to dose reductions and treatment interruptions that may have contributed to limited efficacy in cancer clinical trials.

Similarly, given the role of TGF- β in checkpoint inhibitor resistance, prior attempts have been made to combine checkpoint inhibitors and anti-TGF- β therapies, although they have not been clinically successful. These approaches include bintrafusp alfa, a bifunctional fusion protein that combines a PD-L1 monoclonal antibody and a TGF- β trap. These agents failed to demonstrate sufficient efficacy in large clinical studies, which we believe may be due to insufficient anti-tumor activity within the TME, a result of PD-L1 predominately being expressed in immune tissue rather than within the TME. We believe a tumor-targeted TGF- β inhibitor may differentiate in its ability to deliver potent anti-tumor activity directly within the TME and minimize toxicity, where untargeted approaches may have struggled.

Our Solution: BCA101, a Novel Bifunctional Antibody

BCA101 is a bifunctional antibody that combines the well-established biologies of two targets—the anti-EGFR antibody, cetuximab, fused to the extracellular domain of TGF- β receptor 2, or TGF- β R2. As indicated in Figure 4 below, BCA101 was designed to use EGFR-binding to deliver potent anti-TGF- β therapy directly to EGFR-expressing tumors, potentially removing circulating TGF- β and neutralizing its signaling activity using a strategy known as a “ligand trap”. We believe that localized TGF- β inhibition within the TME has the potential to increase its anti-tumor efficacy and durability, while limiting systemic toxicity. We also deliberately chose EGFR as the tumor-targeting antigen for a TGF- β ligand trap given academic literature support of potential synergistic mechanisms of TGF- β blockade and EGFR signaling inhibition.

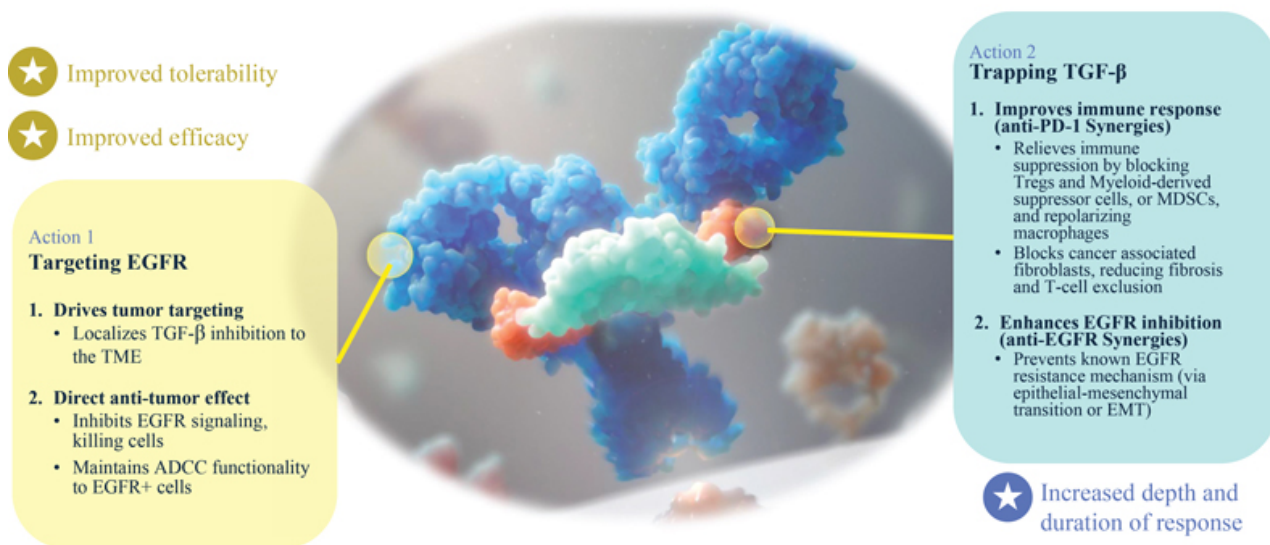


Figure 4. Schematic of intended mechanism of action of BCA101 within the TME to overcome anti-EGFR and anti-PD-1 drug resistance

BCA101 was designed to overcome key shortcomings of prior approaches to targeting EGFR and TGF- β

Specifically, we believe that BCA101 is differentiated from previous and existing approaches given the following:

- **BCA101 localizes TGF- β inhibition directly to EGFR expressing tumor cells.** We believe this will lead to higher concentrations within the TME to increase the inhibition, reduce overall dose and enhance tolerability.
- **BCA101 may help prevent acquired resistance to EGFR-targeted therapies.** Dual targeting of TGF- β alongside EGFR may prevent key resistance mechanisms driven by upregulation of TGF- β and may drive durable tumor responses.
- **BCA101 synergizes with anti-PD-1 therapies.** Targeting TGF- β directly in the TME may relieve immune cell suppression and exclusion and enhance both the immune response as well as the activity of anti-PD-1 therapies.

BCA101 simultaneously binds both EGFR and TGF- β 1 with high specificity and drives improved anti-tumor activity

As depicted in Figure 5 below, BCA101 has a similar affinity for EGFR as cetuximab and the same selectivity for TGF- β 1, the cancer-associated isoform of TGF- β , as TGF- β R2-Fc. As illustrated in the graphic on the right in Figure 5 below, in a head-to-head study it was demonstrated that BCA101 is differentiated in its ability to simultaneously bind to both EGFR and TGF- β 1, while no such binding to TGF- β 1 was observed when cetuximab was used in place of BCA101.

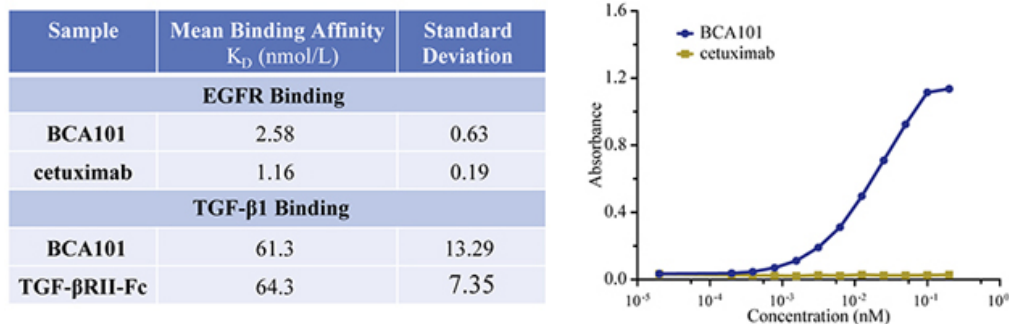


Figure 5. BCA101 has potent binding affinities for both EGFR and TGF- β 1

Furthermore, Figure 6 below illustrates that in a cutaneous cell carcinoma cell line xenograft model, treatment with BCA101 showed improved anti-tumor activity compared to both cetuximab monotherapy and to the combination of cetuximab with an equimolar TGF- β R2-Fc construct. This demonstrates the improved anti-tumor activity associated with the bifunctional nature of BCA101 driving the localization of anti-TGF- β activity to the TME through an EGFR-directed approach.

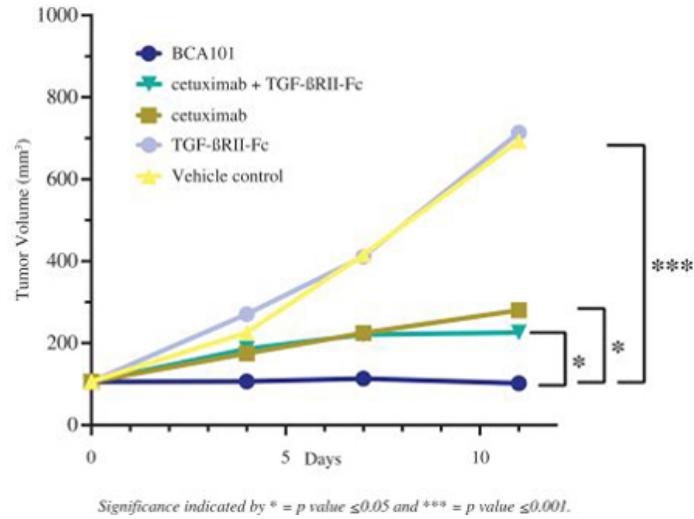


Figure 6. BCA101 showed improved anti-tumor activity in a cutaneous cell carcinoma cell line xenograft model compared to cetuximab or the combination of cetuximab and TGF-βRII-Fc

Clinical biomarker data demonstrates BCA101 inhibits TGF-β in tumors

Biomarkers sampled from patients treated with BCA101 in our Phase 1/1b trials demonstrated direct TGF-β inhibition within the TME and support BCA101’s tumor targeted inhibition. Treatment with BCA101 monotherapy at doses greater than 750mg led to statistically significant reductions in phospho-SMAD2, or pSMAD2, which is a direct downstream biomarker of the TGF-β pathway. Figure 7 below depicts a representative immunohistochemistry, or IHC, slide derived from patient tumor biopsies both prior to and after one dose of 1000mg of BCA101 monotherapy. Importantly, to our knowledge, this biomarker data represents the first definite demonstration of pSMAD2 inhibition in patient tumors by a TGF-β inhibitor.

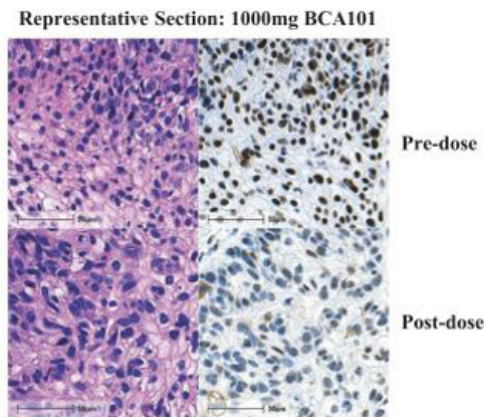


Figure 7. Representative IHC slide showing statistically significant reduction in pSMAD2 from pre-dose to post-dose at 1000mg of BCA101 monotherapy in solid tumors

Preclinical in vivo models demonstrate BCA101 may have an enhanced ability to prevent tumor relapse compared to cetuximab

Preclinical experiments in patient derived xenograft models of EGFR-expressing treatment-naïve HNSCC tumors demonstrate that BCA101 may have an enhanced ability to prevent tumor relapse compared to cetuximab. While both agents show significant reductions in tumor growth, treatment with BCA101 demonstrates sustained anti-tumor effects in a treatment-free, or relapse, phase post day 28. This is demonstrated in Figure 8 below in which 5 out of 10 mice receiving cetuximab had a tumor relapse post day 28 that was not observed for those receiving BCA101. We believe the prevention of relapse may be attributable to the TGF- β arm of BCA101, which is consistent with the mechanistic rationale behind BCA101’s design in which inhibiting TGF- β may prevent acquired resistance to anti-EGFR therapy and result in durable anti-tumor activity.

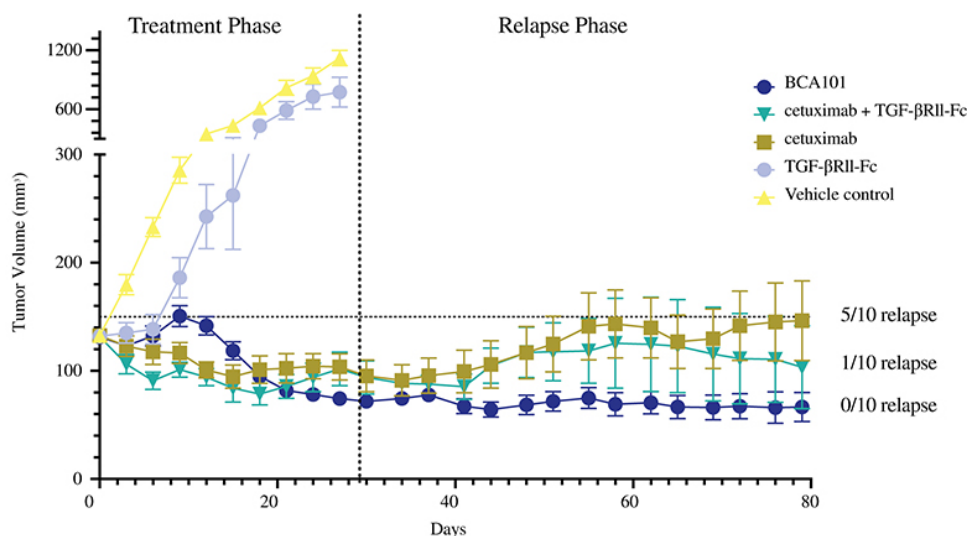


Figure 8. BCA101 demonstrates sustained anti-tumor effects in a patient-derived HNSCC xenograft model compared to cetuximab

BCA101 synergizes with anti-PD-1 therapies, with anti-tumor activity superior to other anti-EGFR therapies in preclinical models

To assess the synergy between BCA101 and anti-PD-1 therapies, we developed two cancer mouse models, in which mice were dosed with an anti-PD-1 antibody in combination with either BCA101 or cetuximab. These preclinical data were published in *Cancer Research*, showing that treatment with BCA101 led to an improved response as compared to cetuximab combination. We believe this data supports the ability of BCA101 to prevent TGF- β from inducing resistance to EGFR-directed therapy and TGF- β -driven immunosuppression.

BCA101 Clinical Development Guided by Strong Biologic Rationale

We believe BCA101 has the potential to provide meaningful clinical benefit in solid tumors where there is a strong biologic rationale for the dual inhibition of both EGFR and TGF- β , such as head and neck cancers, colorectal cancer and other squamous cell carcinomas which typically overexpress EGFR and TGF- β pathways.

HNSCC background

Head and neck cancer accounts for approximately 4% of all cancers in the United States with over 90% of cases presenting with squamous cell origin. As depicted in Figure 9 below, HNSCC commonly originates in the mouth and throat, from the mucosa of the oral cavity, oropharynx, hypopharynx and larynx. It is estimated that by 2030 there will be approximately one million new cases of HNSCC worldwide annually. At the time of diagnosis, an estimated 10% of patients have metastatic disease, and up to 30% of additional patients develop a recurrence or metastases over time after initial treatment for advanced HNSCC. The median survival of patients with local-regional recurrences or distant metastases is approximately 12 months.

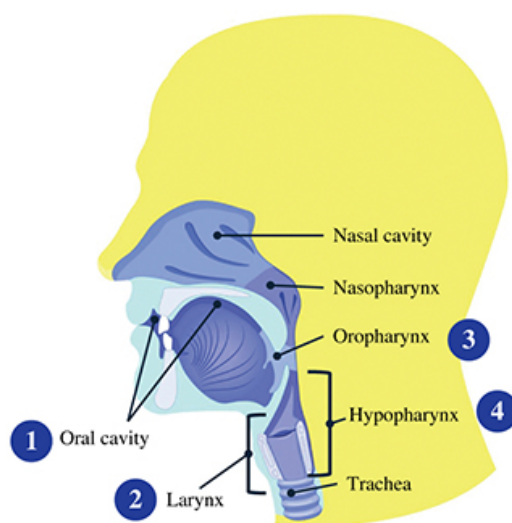


Figure 9. Subtypes of HNSCC by primary tumor origin. Numbered subtypes indicate where BCA101 is currently being tested.

Most cases of HNSCC are believed to arise from mutations that accumulate due to carcinogenic exposure, such as tobacco smoke or by HPV. An estimated 80% of cases of R/M HNSCC are HPV-negative, with testing for HPV status typically only being conducted in tumors originating from the oropharynx. HPV-negative patients have significantly worse outcomes compared with HPV-positive patients. HPV-negative HNSCC tumors typically recur locally and are associated with an increased risk of fatal tumor bleeding, excruciating pain and difficulty swallowing. Thus, there is a significant unmet need for therapies with a durable anti-tumor response in this population. HPV-negative HNSCC is also associated with a higher rate of genomic instability resulting in an increased resistance to therapy.

Treatment of R/M HNSCC

The standard of care first-line therapy for R/M HNSCC is determined by CPS which corresponds to the number of PD-L1 positive cells in relation to the total number of viable tumor cells. Patients with high CPS scores tend to respond better to PD-1 checkpoint inhibitors, as observed across multiple tumor types. In R/M HNSCC, pembrolizumab monotherapy is recommended for patients with a CPS greater than or equal to one. Pembrolizumab combined with platinum and 5-fluorouracil is recommended for patients with any PD-L1 status. The addition of chemotherapy to pembrolizumab increases the response rate; however, it also significantly reduces the duration of response while increasing toxicity and leads to roughly equivalent median OS with both treatments. For patients with a CPS less than one and no PD-L1 expression within their TME, the typical standard of care is the EXTREME regimen, a combination of cetuximab and chemotherapy, which has low response rates and survival, as well as a difficult tolerability profile.

The Phase 3 KEYNOTE-048 trial conducted by Merck & Co investigated pembrolizumab as a monotherapy or in combination with chemotherapy, compared to cetuximab with chemotherapy in first-line R/M HNSCC. The pembrolizumab monotherapy and pembrolizumab and chemotherapy combination response rates of 19% and 36%, respectively, were comparable to the 36% ORR for cetuximab and chemotherapy combination in patients with CPS greater than or equal to one. In these patients, pembrolizumab monotherapy and in combination with chemotherapy led to median OS of 12.3 and 13.0 months, respectively, compared to 10.7 months in the active control arm. While this represents a step forward, there remains significant unmet need in R/M HNSCC for more efficacious therapies that can extend survival, especially for chemotherapy-free alternatives with superior tolerability.

TGF- β expression may limit the effectiveness of HNSCC therapies

Immune checkpoint inhibitors, such as pembrolizumab, activate T cells to attack tumors and their efficacy is dependent on the number of mutations in the tumor. Tumors with more mutations are easier to recognize and are attacked by T cells, thus are the types of tumors that respond more favorably to immune checkpoint inhibitors. Despite the high mutation load in HPV-negative HNSCC, monotherapy with immune checkpoint inhibitors is associated with relatively low ORR compared to other indications such as NSCLC.

Similar observations of poor response rates have been reported for cetuximab in R/M HNSCC. EGFR is expressed in greater than 90% of HNSCC tumors and its overexpression is correlated with decreased survival, resistance to radiation, local treatment failure and increased distant metastasis. In R/M HNSCC, only 13% of patients respond to cetuximab monotherapy, suggesting that there is some form of intrinsic resistance. Third-party clinical studies have demonstrated a statistically significant positive correlation in EGFR-overexpression in HPV-negative HNSCC tumor biopsies.

As depicted in Figure 10 below, third-party clinical studies have shown plasma samples from patients with HPV-negative HNSCC to have significantly higher levels of TGF- β than non-HNSCC controls, whereas TGF- β levels in HPV-positive HNSCC patients are not significantly different than those of controls.

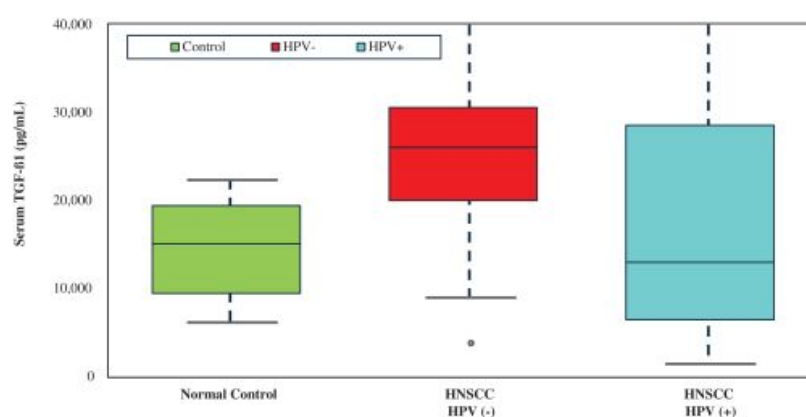


Figure 10. Serum levels of TGF- β are elevated in HPV-negative HNSCC

Therefore, due to the link between EGFR and TGF- β levels and their HPV status, we believe that the dual-inhibition of EGFR and TGF- β signaling in HPV-negative R/M HNSCC has the potential to improve clinical responses and delay or prevent emergence of resistance. Furthermore, third-party studies have shown that TGF- β is an emerging biomarker of resistance to anti-PD-L1 and anti-EGFR-based therapy in advanced HNSCC. Thus, we believe there is strong rationale to pursue the clinical development of BCA101, an anti-EGFR and TGF- β -trap bifunctional antibody combined with anti-PD-L1 therapy, such as pembrolizumab, in HNSCC and other squamous cell carcinomas.

Ongoing Phase 1/1b Trial

BCA101 Phase 1/1b trial overview

We have conducted an open-label Phase 1/1b trial in patients with EGFR-driven solid tumors which remains open and ongoing. This trial has the goal of establishing safety and tolerability, as well as the recommended dose for expansion for both BCA101 monotherapy and BCA101 in combination with pembrolizumab across various tumor types. As illustrated in Figure 11, a total of 46 patients with EGFR-driven advanced solid tumors were given increasing doses of BCA101 in monotherapy. The first dose tested was 64mg weekly increasing to 1500mg weekly using a “3+3” dose escalation trial design. In combination with pembrolizumab, 15 patients with late-line R/M HNSCC and squamous cancer of the anal canal were dosed. The lowest dose tested in combination with pembrolizumab was 240mg of BCA101 weekly. Across both monotherapy and in combination, a maximum tolerated dose was not reached. However, an initial recommended dose of 1500mg weekly is being assessed across multiple dose expansion cohorts, including a cohort of patients with first-line R/M HNSCC in combination with pembrolizumab. This dose was chosen based on safety, tolerability and preliminary efficacy as depicted in the bottom graph in Figure 11.

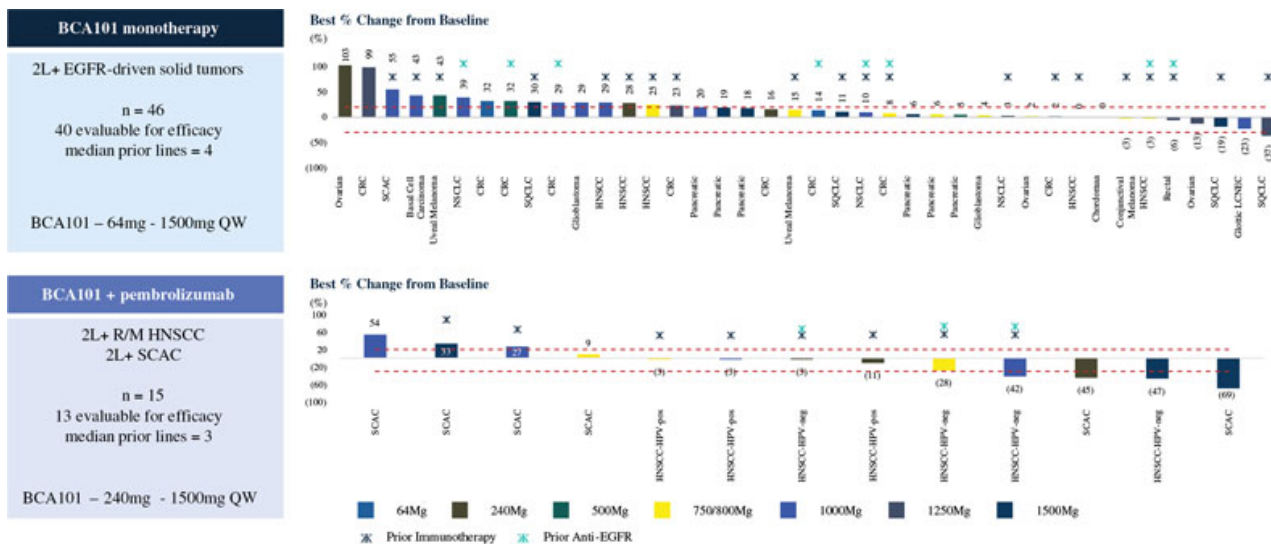


Figure 11. Schematic of study of safety and tolerability of BCA101 monotherapy and in combination therapy in patients with EGFR-driven advanced solid tumors across dose escalation cohorts. Preliminary efficacy from dose escalation cohorts with BCA101 in monotherapy and in combination with pembrolizumab

BCA101 clinical studies in R/M HNSCC

Our decision to pursue the potential of combination therapy came from both our preclinical rationale and results showing synergy between BCA101 and pembrolizumab; and from two third-party investigator-sponsored trials, or ISTs, which showed that a combination of cetuximab and PD-1 checkpoint inhibitors in R/M HNSCC led to improved ORR compared to checkpoint inhibitor monotherapy. Importantly, though both of these ISTs are single-arm studies, they were the first demonstration that an approximate doubling in ORR could translate to an increased mPFS, and most notably, significant improvement in OS in first-line R/M HNSCC. The first IST, a 2021 publication in *Lancet Oncology*, reported an ORR of 48% in a clinical trial assessing cetuximab in combination with pembrolizumab in 33 patients. This was followed by a second IST published in 2022 in *Clinical Cancer Research*, which reported an ORR of 37% in a trial of cetuximab and nivolumab in 43 patients. These studies showed a 20-month and 18-month mOS, respectively, an improvement on the 12-month benchmark with pembrolizumab, and support the notion that the addition of anti-EGFR based therapy does not dampen durability of response or OS like a chemotherapy-containing regimen. Consistent with our hypothesis,

we began to observe an encouraging objective response rate in late-line R/M HNSCC patients when treated with BCA101 and pembrolizumab. Based on these multiple data sets, we prioritized this combination treatment to allow for acceleration of its clinical development.

Our decision to rapidly move BCA101 into first-line therapy for R/M HNSCC in combination with pembrolizumab is aligned with the published goals of the Project FrontRunner initiative from the Oncology Center of Excellence at the FDA. The goals of this initiative include identifying candidate drugs that are appropriate to initially develop for the treatment of early metastatic disease, taking into account clinical, scientific, regulatory and operational considerations. We believe developing BCA101 as a first-line therapy may allow us to further address the significant unmet need in HNSCC while also potentially increasing durability and survival outcomes consistent with our biologic rationale.

Data from our Phase 1/1b dose expansion cohort evaluating 1500mg of BCA101 in combination with pembrolizumab in efficacy-evaluable first-line R/M HNSCC patients with a CPS greater than or equal to one was first presented in an oral presentation at an American Society of Clinical Oncology meeting in June 2023. As depicted in Figure 12 below, we demonstrated a meaningful 54% (21/39) ORR across both HPV-negative and HPV-positive R/M HNSCC, a notable increase compared to published historical data for pembrolizumab monotherapy. We also observed a markedly higher ORR of 64% (18/28) in the HPV-negative subset. This is consistent with the HPV-negative subset having elevated levels of EGFR and TGF-b where we believe BCA101 has potential to achieve differentiated clinical outcomes.

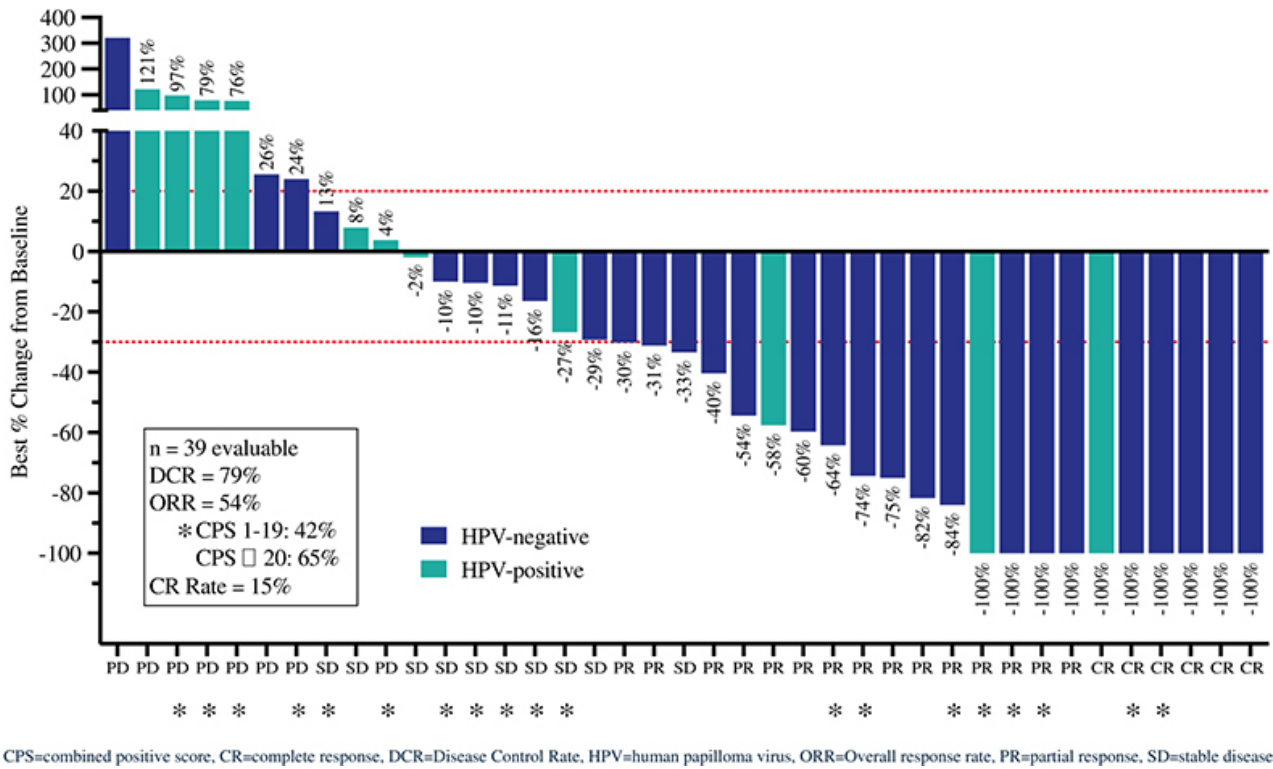


Figure 12. Anti-tumor responses in HNSCC patients, treatment-naïve in the R/M setting, treated with BCA101 in combination with pembrolizumab

As depicted in Figure 13 below, in the HPV-negative subset, response rates of more than 50% were observed in both the CPS 1 through 19 and CPS greater than or equal to 20 subgroups. This is notable as pembrolizumab is known to have a lower efficacy in the CPS1-19 subset. We also observed that 18% (5/28) of HPV-negative patients achieved a CR and several other patients achieved deep partial responses, including 5

other patients with responses greater than 80%. The CR rate we observed in this cohort appears to be significantly higher compared to those previously reported in the ISTs of cetuximab in combination with pembrolizumab or nivolumab, as well as the KEYNOTE-048 study with pembrolizumab, of approximately 3%. We believe these deep responses and high CR rate are driven by the TGF- β arm of BCA101, which we believe, based on our hypothesized mechanism of action, is expected to synergize with pembrolizumab by remodeling the TME and activating the immune system (see Figure 4).

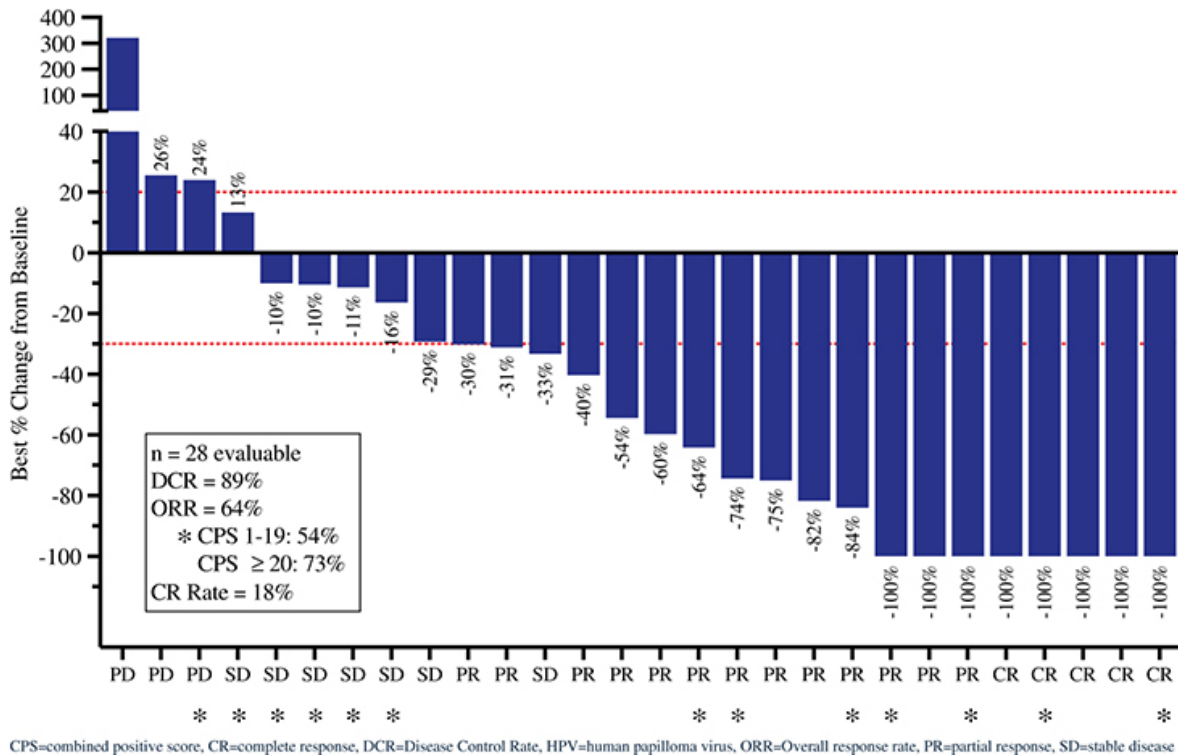


Figure 13. Anti-tumor responses of HPV-negative HNSCC patients treated with BCA101 and pembrolizumab

In addition to the high ORR and deep partial responses, we observed that the responses in the combination trial were durable and suggestive of enhanced immunological memory. As depicted in Figure 14 below, the mPFS in HPV-negative subjects was 9.8 months, a threefold increase in PFS benefit when compared to published historical data for pembrolizumab monotherapy, and superior to the data published for cetuximab and anti-PD-1 combination ISTs. Interestingly, we observe patients responding to therapy after 4 months and several responses deepening over time, some even converting to CRs after 6 months of treatment. We believe these trends in the data are consistent with our mechanism of action related to the TGF- β inhibition within the TME. We aim to replicate this Phase 1b data in a pivotal randomized Phase 2/3 trial as we believe BCA101 in combination with pembrolizumab could be established as the new chemotherapy-free standard of care for HPV-negative first-line R/M HNSCC.

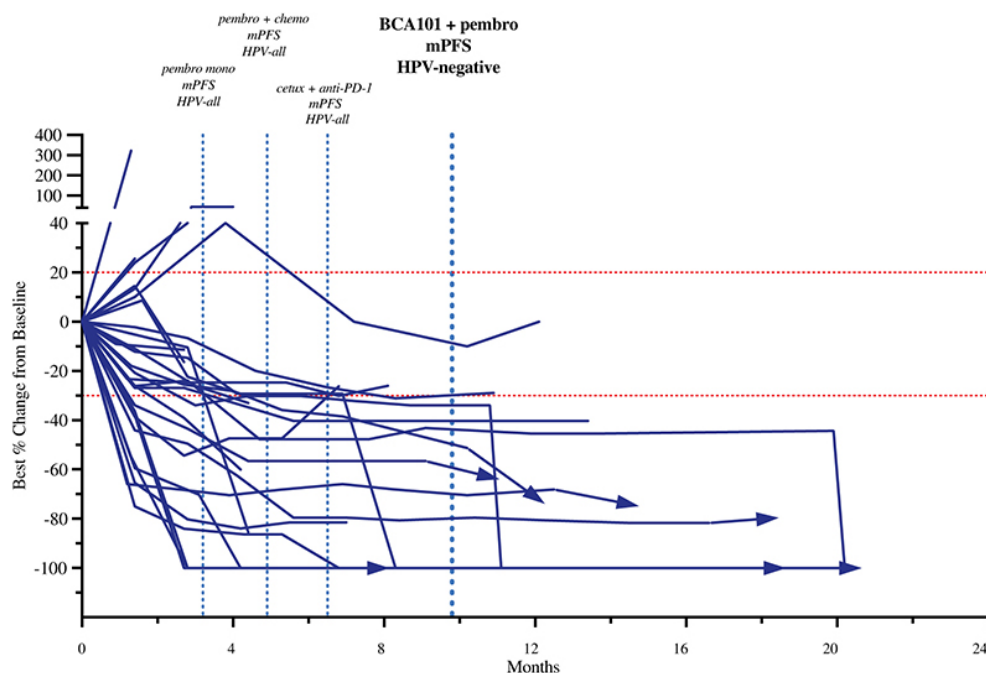


Figure 14. HPV-negative R/M HNSCC patients treated with BCA101 in combination with pembrolizumab had durable responses

BCA101 has been generally well-tolerated with a favorable tolerability profile

BCA101 has demonstrated a favorable tolerability profile in this Phase 1/1b trial in combination with pembrolizumab. Across all cohorts to date, approximately 200 patients received at least one dose of BCA101. The most frequent adverse event suspected to be related to treatment with BCA101 was acneiform rash, which is an adverse event that is also observed in approximately 80% of HNSCC patients treated with cetuximab. It is mechanistically related to anti-EGFR activity and is typically well mitigated by treating physicians with the use of steroids and other topicals. Adverse events associated with TGF- β inhibition include mostly low-grade mucosal bleeding not requiring any medical intervention. Most importantly, there were no deaths determined to be related to BCA101 monotherapy or combination treatment. The 1500mg BCA101 weekly dose, which most R/M HNSCC patients received, resulted in approximately 150% greater molar concentration of cetuximab than the maximum approved dose of cetuximab. We believe that the anti-TGF- β activity of BCA101 may dampen the severity of acneiform rash through its impact on neutrophil trafficking, enabling patients to tolerate this higher dose, which may in turn help drive improved efficacy.

The safety profile of BCA101 + pembrolizumab in our Phase 1/1b dose expansion cohort evaluating 1500mg of BCA101 in combination with pembrolizumab in efficacy-evaluable first-line R/M HNSCC patients with a CPS greater than or equal to one was generally well-tolerated. With a median safety follow-up of at least 11.7 months and a maximum follow up of 25 months, we observed EGFR-related adverse events of dermatitis acneiform in 76% of patients, with 12% of these being Grade 3 or Grade 4. The treatment-related adverse events, or TRAEs, leading to discontinuation of BCA101 and/or pembrolizumab was 12%, markedly lower than historical pembrolizumab combinations, including lenvatinib or chemotherapy, which showed TRAEs leading to discontinuation rates of 28% and 33%, respectively.

BCA101 Phase 2/3 trial in 1L R/M HNSCC allows for efficient path-to-market

As a result of our discussions with the FDA, we believe that BCA101 has a path to accelerated approval using an ORR-based interim endpoint with confirmatory approval based on an OS endpoint. We have designed a double-blinded placebo-controlled pivotal Phase 2/3 trial of BCA101 in combination with pembrolizumab as a first-line therapy in R/M HNSCC excluding patients with HPV-positive OPSCC. The total study will enroll approximately 750 patients, which we believe is sufficiently powered to achieve results that may lead to regulatory approval. As seen in Figure 15 below, this registrational study is designed with a dose selection run-in of approximately 20 patients per arm, consistent with the objectives of the FDA’s Project Optimus. Project Optimus is an initiative by the FDA’s Oncology Center for Excellence to move forward with a dose-finding and dose optimization paradigm across oncology that emphasizes selection of a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. We expect to initiate this trial by [redacted] and project that the ORR interim analysis conducted on approximately 415 patients may occur by [redacted]. As part of this study, we intend to source our own doses of pembrolizumab.

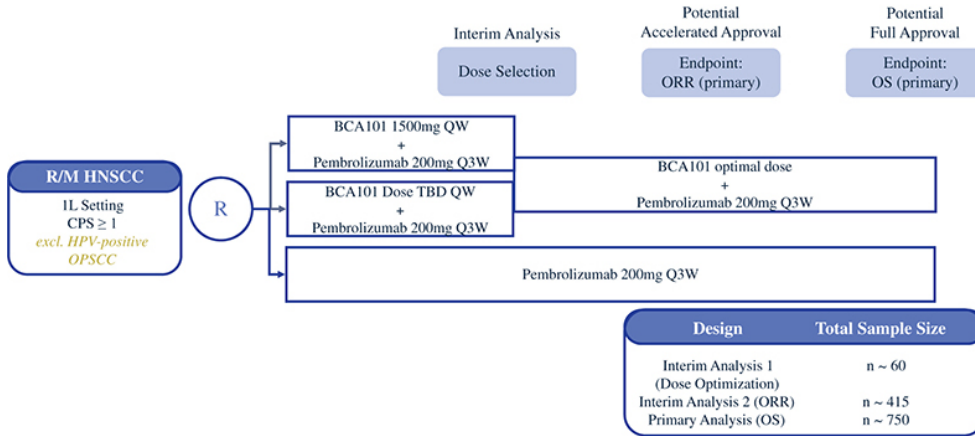


Figure 15. Schematic of BCA101 + pembrolizumab Phase 2/3 trial design

Potential expansion opportunities for BCA101

We believe that there is potential to expand the use of BCA101 to other populations of HNSCC patients. Preliminary data from our dose escalation cohort in combination with pembrolizumab have shown durable responses in patients who are refractory to both cetuximab and pembrolizumab, and in patients with a CPS of zero. These early data suggest an ability for BCA101 to synergize with pembrolizumab in checkpoint-refractory tumors, and we are looking to initiate an expansion cohort in patients with HPV-negative R/M HNSCC with a CPS of zero. Should we see responses beyond what is typically expected with chemotherapy regimens, we believe there is an opportunity to expand the development of BCA101 in combination with pembrolizumab to the approximately 20% of the R/M HNSCC that do not express PD-L1 and provide a chemotherapy-free alternative. In addition, the encouraging anti-tumor activity of BCA101, specifically its durability and its tolerability profile, suggest that there is potential to develop it for the treatment of locally advanced HPV-negative HNSCC or in the neoadjuvant or adjuvant setting.

Beyond HNSCC, we believe BCA101 has the potential to provide meaningful clinical benefit in other squamous cell carcinomas where there is a strong biologic rationale for the dual inhibition of both EGFR and TGF- β . We have demonstrated preliminary activity of BCA101 as a monotherapy in CSCC. As shown in Figure 16, in the monotherapy arm of our ongoing Phase 1/1b trial, BCA101 showed a preliminary 42% (5/12) ORR as

a second-line therapy in patients with CSCC who were refractory to a PD-1 checkpoint inhibitor, a population in which historical response rates are approximately 5% with chemotherapy. This cohort continues to enroll patients and we expect to share updates to this preliminary data set at future medical meetings.

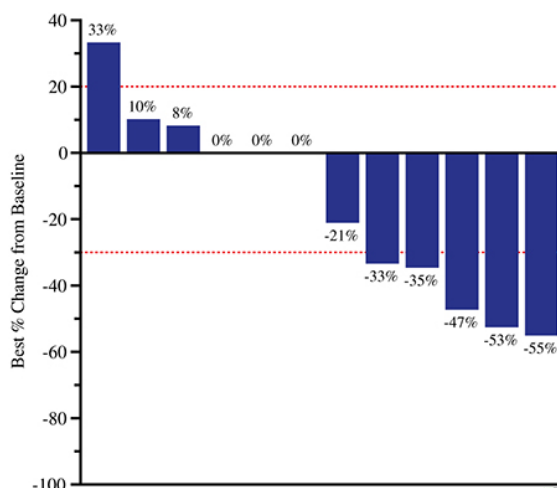


Figure 16. BCA101 monotherapy led to a preliminary 42% (5/12) ORR in 12 patients

We believe that there is potential to develop BCA101 both in monotherapy and in combination for the treatment of other EGFR-expressing tumors, such as colorectal cancers where cetuximab has already demonstrated clinical efficacy, and where TGF- β inhibition has the potential to improve upon both the efficacy and durability of existing therapies. Preclinical data we presented at the 2023 Society for Immunotherapy of Cancer annual meeting provide early validation for the combination of BCA101 and KRAS mutant inhibitors to delay acquired resistance in colorectal cancer. We intend to initiate additional expansion cohorts in colorectal cancer by

Competition

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new products and technologies. We compete directly with companies dedicating their resources to advance novel therapies for the treatment of cancer. We face substantial competition from multiple sources, including large pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. We anticipate that we will continue to face increasing competition as new therapies, technologies and data emerge within the field of oncology and, more specifically, for the treatment of HNSCC.

We expect to compete with commercially available therapies for the treatment of HNSCC, including pembrolizumab (marketed as Keytruda by Merck & Co); the combination of pembrolizumab, platinum chemotherapy and 5-fluorouracil; and the combination of cetuximab (marketed as Erbitux by Eli Lilly in the U.S. and by Merck KGaA outside of the U.S.), platinum chemotherapy and 5-fluorouracil. In addition, there are numerous companies that are developing new treatments for HNSCC, including Merck & Co, Pfizer Inc., Genmab A/S, Exelixis, Inc., Merus N.V., Iovance Biotherapeutics, Inc., Kura Oncology, Inc. and ALX Oncology Holdings, Inc.

Some of our competitors have significantly greater financial resources and expertise in areas such as research and development, manufacturing, regulatory protocols and marketing. Mergers and acquisitions in the

pharmaceutical, biopharmaceutical and biotechnology industries may result in a concentration of incremental resources amongst a fewer number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with larger and more well-established companies. These companies also compete with us in the recruitment and retainment of top qualified scientific and/or management personnel, establishment of clinical trial sites and patient registration for clinical trials and acquisition of technologies complementary to, or necessary for, our programs.

If our product candidates do not offer sustainable advantages over other available products, we may not be able to successfully compete against current and future competitors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key factors that will ultimately affect the success of our bifunctional therapies, if approved, are likely their safety, efficacy, convenience and cost.

Contract Transfer And License Agreement with Biocon

On October 1, 2019, we entered into a Contract Transfer and License Agreement, or the Biocon Agreement, with Biocon Limited, or Biocon. Pursuant to the Biocon Agreement, we and Biocon agreed that Biocon would grant us a license, with the right to grant and authorize sublicenses to make, use, sell, offer to sell, import, and otherwise exploit certain fusion protein products. Under the Biocon Agreement, Biocon also assigns to us the “Assumed Contracts,” which include master services agreements, an authorization letter, an evaluation license agreement, consultancy agreements, a research agreement and a quality agreement.

Until ownership of each Assumed Contract has been fully transferred to us, Biocon holds the benefit of that Assumed Contract in trust for us, exercises its rights (which we may direct or approve in writing), and accounts to us any sums (or other benefits) which arise under such Assumed Contract. Biocon also maintains its responsibility to uphold any obligations under the relevant Assumed Contract.

In connection with the Biocon Agreement, we paid INR 550 million as consideration for the license grant. Under the Biocon Agreement, Biocon is required on a calendar quarterly basis to deliver any additional materials or know-how relating to the product up until a mid-single digit anniversary from the effective date of the Biocon Agreement. In the event of an acquisition of all or substantially all of our assets and business by a third party, this obligation shall terminate. Additionally, we have assumed sole responsibility for complying with any post-approval developments and post-marketing activities such as routine and non-routine pharmacovigilance monitoring and post-marketing surveillance for the products – including any and all clinical trials.

Clinical Trial Collaboration And Supply Agreement with MSD

On May 19, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement, or the MSD Agreement, with MSD International GmbH, or MSDIG, and MSD International Business GmbH, MSDIB, and collectively with MSDIG, MSD. Pursuant to the MSD Agreement, we provide BCA101 and MSD provides pembrolizumab to be used in combination in a clinical trial sponsored by us. The clinical trial is a First-in-Human, Phase 1/1b, Open-label, Multicenter Study intended to characterize the safety, tolerability and recommended dose of single agent BCA101 and combination BCA101 plus pembrolizumab. To facilitate such collaboration activities and information exchange and pursuant to the MSD Agreement, we and MSD created a joint development committee with an equal number of representatives from each party.

Pursuant to the MSD Agreement, all clinical data resulting from the portion of the clinical trial involving the combination of BCA101 and pembrolizumab is jointly owned by both us and MSD. We own all clinical data resulting from the part of the clinical trial involving BCA101 alone or in combination with other treatments that are not pembrolizumab, and MSD owns all clinical data resulting from the part of the clinical trial involving pembrolizumab alone or in combination with other treatments that are not BCA101.

The MSD Agreement also sets forth our regulatory responsibilities as the sponsor of the clinical trial – such as obtaining all necessary regulatory approvals, maintaining reports and other related documentation in a scientific and legally compliant manner, and handling safety reporting. Prior to dosing any patient with MSD’s compound, we are required to organize and invite MSD to attend a safety review meeting to discuss the most recent clinical safety data (and other data reasonably requested by MSD to evaluate the safety of the proposed study arms). We have also been responsible for preparing the patient informed-consent form for MSD’s compound study (in consultation with MSD) and transmitting data on severe adverse events from the MSD compound study to MSD. Each party is responsible for its own internal costs and expenses to support the clinical trials.

The term of the MSD Agreement commenced on May 19, 2022 and will expire once we deliver the final documents, signifying the completion of the clinical trial, unless the MSD Agreement is earlier terminated in accordance with the terms of the MSD Agreement. Pursuant to the MSD Agreement, MSD may terminate the MSD Agreement early if it believes its products are being used unsafely. Either party may terminate the MSD Agreement early for breach, regulatory action, force majeure, or concerns about patient safety. Additionally, either party may terminate the MSD Agreement early if one is planning to discontinue development of its own compound for medical, scientific or legal reasons.

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that we believe to be commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a nonprovisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory

requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. The restoration period cannot be longer than five years, and the restoration period may not extend the patent term beyond 14 years from the date of FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on one issued patent covering each of those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

Our policy is to file patent applications to protect technology, inventions and improvements to inventions that may be commercially important to the development of our business. We seek patent protection in the United States and foreign countries for a variety of technologies, including our BCA101 product candidate and methods of treating cancer using the same.

BCA101

We have an exclusive license from Biocon Limited to one patent family directed to BCA101 and other fusion proteins. As of May 23, 2024, the patent contains one U.S. patent directed to BCA101 composition of matter; one U.S. patent directed to methods of using BCA101; one European patent directed to BCA101 composition of matter and its use; and one issued patent in each of Australia, Canada, India, Japan, New Zealand, Russia, Malaysia, and the United Arab Emirates, each related to BCA101. Each of the U.S. and foreign patents is expected to expire in 2033; in each instance provided that all appropriate maintenance fees are paid and not including any patent term adjustment, patent term extension, Supplementary Protection Certificate, or SPC, or the like. The patent family also contains a number of pending patent applications in the U.S. and several foreign countries. Any patents that issue based on these patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2033, not including any patent term adjustment, patent term extension, SPC, or the like.

As of May 23, 2024, we also solely own a patent portfolio containing pending patent applications that, if issued, may provide additional intellectual property protection for BCA101.

As of May 23, 2024, we solely own one patent family directed to formulations of BCA101 that contains pending patent applications in the U.S. and several foreign countries. Any patents that issue based on these patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2041, not including any patent term adjustment, patent term extension, SPC, or the like.

As of May 23, 2024, we solely own one patent family directed to methods of using BCA101 in combination with programmed cell death protein 1, or PD1, targeting agents that contains pending patent applications in the U.S. and several foreign countries. Any patents that issue based on these patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2041, not including any patent term adjustment, patent term extension, SPC, or the like.

As of May 23, 2024, we solely own one patent family directed to methods of using BCA101 in combination with Kirsten ras oncogene homolog, or KRAS, targeting agents that contains a pending U.S. patent application, a pending PCT patent application, and a pending Taiwanese patent application. Any patents that issue based on these patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2044, not including any patent term adjustment, patent term extension, SPC, or the like.

As of May 23, 2024, we solely own one patent family relating to methods of treating glioblastoma that contains a pending U.S. provisional application. Any patents that issue based on this patent application, if granted and all appropriate maintenance fees paid, are expected to expire in 2044, not including any patent term adjustment, patent term extension, SPC, or the like.

Manufacturing

We have leveraged multiple third-party manufacturers to support the manufacturing of BCA101 for clinical trials and, if we receive regulatory approval, we intend to rely on such third parties for commercial manufacture. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We believe this strategy will enable us to maintain a nimble, efficient, and effective working model without making significant internal capital investments. We are focused on developing high-yield and scalable processes and analytical methods for the manufacture of BCA101. We believe our manufacturing scale will support drug supply for our future clinical trials and commercial demand for BCA101 to treat R/M HNSCC squamous cell carcinoma, if approved. We currently obtain our supplies from third-party manufacturers on a purchase order basis and do not have any long-term supply agreements in place. To de-risk our supply chain, and as we advance toward potential commercialization, we intend to enter into long-term supply agreements as well as evaluate additional product manufacturing sources.

Government Regulation

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of biological products, such as those we are developing. In addition, some government authorities regulate the pricing of such products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Review and Approval for Licensing Biologics in the United States

In the United States, U.S. Food and Drug Administration, or the FDA, regulates biological products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. FDA approval is required before any biological product can be marketed in the United States. Biological products are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions or other consequences, including the FDA's refusal to allow us to proceed with clinical testing, issuance of clinical holds for planned or ongoing studies, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, issuance of untitled or warning letters, product recalls, product seizures, import detentions or refusals, total or partial suspension of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution. Any such action could have a material adverse effect on us.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests and nonclinical animal studies in compliance with applicable good laboratory practices, or GLP, requirements;

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- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials may begin in the United States and must be updated annually;
- approval by an independent institutional review board, IRB, or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the product candidate for each proposed indication;
- manufacture of the drug substance and drug product in accordance with the FDA's current good manufacturing practice, or cGMP, requirements, along with required analytical and stability testing;
- preparation of and submission to the FDA of a biologics license application, or BLA, requesting marketing approval for one or more proposed indications, that includes sufficient evidence of establishing the safety, purity and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- review of the product application by an FDA Advisory Committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, quality, and strength;
- satisfactory completion of any FDA audits of the nonclinical studies and clinical trial sites to assure compliance with GLPs and GCPs, as applicable, and the integrity of data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act, or the PDUFA, unless exempted; and
- the FDA's review and approval of the BLA.

The nonclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical Studies and Investigational New Drug Application

Before testing any biological product in humans, a product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation, and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational biological product to humans in clinical trials in the United States. The central focus of an IND submission is on the general investigational plan, the protocol(s) for human trials and the safety of trial participants. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

At any time during the initial 30 day IND review period or while clinical trials are ongoing under the IND, the FDA may impose a partial or complete clinical hold. Clinical holds may be imposed by the FDA when there is concern for patient safety, and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing and controls or where there is non-compliance with regulatory requirements. A clinical hold would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. A separate submission to an existing IND must also be made for each successive clinical trial to be conducted, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Additionally, approval must also be obtained from each clinical trial site's IRB, before the trials may be initiated and the IRB must monitor the trial until completed. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries, including on clinicaltrials.gov.

The clinical investigation of a biological product is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

Phase 1. The investigational product is initially introduced into healthy human subjects or, in the case of some products designed to address severe or life-threatening diseases, patients with the target disease or condition. These trials are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate safety, purity and potency, to evaluate the overall benefit-risk profile of the investigational product, and to provide an adequate basis for physician labeling.

Phase 4. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval or a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the biological product. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an

independent group of qualified experts organized by the clinical trial sponsor, known as a data and safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

A sponsor of an investigational biological product for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational biological product. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational biological product or, as applicable, 15 days after the biological product receives a designation as a breakthrough therapy or fast track product.

Concurrent with clinical trials, sponsors usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality, and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 1, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Submission of a BLA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product information is submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs is subject to an application user fee, and the sponsor of an approved BLA is also subject to an annual program fee for each approved biological product on the market. Applications for orphan drug products are exempted from the BLA application fee and may be exempted from program fees, unless the application includes an indication for other than a rare disease or condition.

A BLA must include all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

The FDA conducts a preliminary review of all BLAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. Under the performance goals and policies implemented by the FDA under PDUFA, once a BLA has been submitted, the FDA's goal for novel biological products generally is to review the application within ten months after it accepts the application for filing, or, if the application is granted priority review, six months after the FDA accepts the application for filing. The FDA does not always meet its PDUFA goal dates, and the review process may be extended. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional data, analysis or information that FDA deems a major amendment.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure compliance with GCPs. Material changes in manufacturing equipment, location, or process post-approval, may result in additional regulatory review and approval.

The FDA is required to refer an application for a novel biological product to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on a BLA

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA inspections of nonclinical and clinical trial sites to assure compliance with GLPs or GCPs, the FDA may approve the BLA or issue a complete response letter. Under the PHS Act, the FDA may approve a BLA if it determines the product is safe, pure, and potent, and that the facility in which the product will be manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. If the FDA determines the product meets those standards, it may issue an approval letter authorizing commercial marketing of the biological product with specific prescribing information for specific indications. If the application is not approved, FDA will issue a complete response letter, which indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter will identify the deficiencies that prevent the FDA from approving the application and may require additional clinical data or an additional Phase 3 clinical trial(s), or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval and issue a denial.

The FDA could also approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, program to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan

designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with this position, holding that orphan-drug exclusivity blocked the FDA's approval of the same drug for all uses or indications within the same orphan-designated disease. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that the FDA intends to continue to apply its longstanding interpretation of the regulations to all matters outside of the scope of the *Catalyst* order and will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of orphan drug exclusivity.

Expedited Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates.

New biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase I and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review. An application for a biological

product will receive priority review designation if it is for a biological product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation, and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated Approval

Product candidates studied for their safety and effectiveness in treating serious conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a biologic or indication approved under accelerated approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to FDA for review during the pre-approval period. After 120 days following marketing approval, unless otherwise informed by the FDA, advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Post-Approval Requirements

Biological products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new dosage forms, indications or other labeling claims, are subject to prior FDA review and approval.

Biological product manufacturers are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections for compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Manufacturers and manufacturers' facilities are also required to comply with applicable product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

A biological product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may perform certain confirmatory tests on lots of some products before releasing the lots for distribution.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, or distribution, or may require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may suspend or revoke product license approvals if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. FDA has authority to require post-market studies, in certain circumstances, on reduced effectiveness of a biological product and FDA may require labeling changes related to new reduced effectiveness information. Other potential consequences of a failure to maintain regulatory compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- untitled letters or warning letters;
- imposition of clinical holds on ongoing clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of approved BLAs;
- product seizure or detention, or refusal to permit the import or export of products;
- mandated modification of promotional materials and labeling, and the issuance of corrective information;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- fines, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of prescription drug products, including biological products. These regulations include, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the BLA is approved. Once a BLA is approved, the sponsor can only make those claims relating to safety, efficacy, purity and potency that are consistent with the biological product's approved label. Additionally, promotional materials for prescription drug products must be submitted to the FDA in conjunction with their first use.

In the United States, healthcare professionals are generally permitted to prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those approved by the FDA. The FDA does not regulate the practice of medicine or healthcare providers' choice of treatments; however, FDA restricts manufacturers' communications of off-label uses. If a company, including any agent of the company or anyone speaking on behalf of the company, is found to have promoted off-label uses, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Pediatric Trials and Exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA (or BLA supplement thereto) must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days of an end of Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. Generally, development program candidates designated as orphan drugs are exempt from the above requirements. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA may send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted for a biologic, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for all formulations, dosage forms, and indications of the biologic, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA sponsor's data.

Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or the ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the proposed biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product, can be expected to produce the same clinical results as the reference product and, for products administered multiple times, that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The first biologic submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product is eligible for a period of exclusivity against other biologics submitted under the abbreviated approval pathway during which time the FDA may not determine that another product is interchangeable with the same reference product for any condition of use. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. Products deemed "interchangeable" by the FDA may be readily substituted by pharmacies and such substitution is which are governed by state pharmacy law. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity and enforceability prior to the approval of the biosimilar. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices to regulate the use of biosimilars.

Regulation of Companion Diagnostics

We believe that the success of certain of our product candidates may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), application, grant of a de novo request for classification, or de novo grant, and approval of a premarket approval, or PMA, application.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

For novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, a manufacturer may request a risk-based classification determination, called a “Request for Evaluation of Automatic Class III Designation,” for the device in accordance with de novo classification process. This procedure allows a de novo requester whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Under the FDCA, FDA must make a classification determination for the device that is the subject of a de novo request within 120 days of receipt of the request. However, as specified in FDA’s Medical Device User Fee Amendments of 2022, or MDUFA V, commitment letter, the FDA’s goal is to make a decision on most de novo requests within 150 FDA Days, although in practice the FDA’s review may take significantly longer. During the pendency of FDA’s review, the FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn. The FDA may reject the de novo request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed. In the event the FDA determines that the data and information submitted demonstrate that General Controls or General and Special Controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request and a classification regulation will be established for the device type. When the FDA grants a de novo request for classification, the device is granted marketing authorization and can further serve as a predicate device for a future 510(k) by any person for future devices of that type.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an *in vitro* companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding *in vitro* companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of the FDA's quality system regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like biological product manufacturers, companion diagnostic manufacturers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

European Union/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the

context of the European Union and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial authorization application must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Under the EU Clinical Trials Regulation, this is now done through a single application submitted through the Clinical Trials Information System (CTIS), as described in more detail below.

The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP, the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The content of the BLA filed in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the European Union, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of biological products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trial Approval in the European Union

In April 2014, the European Union adopted the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The Clinical Trials Regulation is directly applicable in all European Union Member States meaning no national implementing legislation in each European Union Member State is required. The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, through the CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have also been established for the assessment of clinical trial applications.

Marketing Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

The European Commission implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area, or the EEA, which is comprised of the Member States of the European Union plus Norway, Iceland, and Lichtenstein. The centralized procedure is administered by the European Medicines Agency, EMA and is compulsory for human medicines that are: derived from certain biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV, AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, advanced therapy medicines (gene therapy, somatic cell therapy or tissue-engineered medicines), and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the European Union, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the European Union.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or the CHMP, is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Prior to obtaining a marketing authorization in the European Union, applicants must demonstrate compliance with all measures included in an EMA-approved pediatric investigation plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The Pediatric Committee of the EMA, or the PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Data and Market Exclusivity in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, during a period of eight years from the date on which the reference product was first authorized in the European Union. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new

therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into European Union law.

The aforementioned European Union rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the European Union on January 31, 2020, and the European Union and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore aligns in many ways with current European Union regulations, however it is likely that these regimes will diverge significantly in the future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of UK and European Union pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of European Union pharmaceutical legislation under the TCA, under a new international recognition procedure which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (*i.e.*, Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the European Union will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and foreign markets, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement for our products from third-party payors, such as government healthcare programs (e.g., Medicare, Medicaid), managed care organizations, private health insurers, health maintenance organizations, and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for patients depending on government or commercial insurance to pay for the costs of prescription medications and other medical products.

In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Factors payors consider in determining reimbursement are based on whether the product is:

- A covered benefit under its health plan;
- Safe, effective and medically necessary;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs (e.g., Medicare, Medicaid), managed care organizations, private health insurers, health maintenance organizations, and other organizations. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party payors are increasingly challenging pharmaceutical prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Further, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Even

if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and impacted by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and could increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other U.S. Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of drug products for which we obtain marketing approval. Arrangements with third-party payors, healthcare providers and physicians, as well as patients and other third parties, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, transparency, consumer protection, and patient data privacy and security laws and regulations, including but not limited to those described below:

- The Anti-Kickback Statute, or AKS, makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward, referrals including the purchase, recommendation, order or prescription of a particular drug for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, patients, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the AKS is violated. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA.
- The federal civil and criminal false claims laws, including the FCA, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal or state health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. The FCA also permits a private individual acting as a whistleblower to bring actions on

behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for allegedly providing kickbacks to providers or patients or causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

- The Civil Monetary Penalties Law, which covers a variety of conduct, often violations under other laws, and includes penalties for violating the AKS, causing the submission of false claims, and offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (e.g., public or private) or making any false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Like the AKS, the Patient Protection and Affordable Care Act, or the ACA, amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, also imposes requirements related to the privacy, security and transmission of individually identifiable health information that may apply to many healthcare providers, physicians, and third-party payors with whom we interact.
- The federal Physician Payments Sunshine Act and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS, under the Open Payments Program, information related to payments or other transfers of value made to physicians (which has the same meaning as under Section 1861(r) of the Social Security Act, which generally includes doctors of medicine, osteopathy, dentists, optometrists, podiatrists and chiropractors who are legally authorized to practice by a state), to certain non-physician providers such as physician assistants and nurse practitioners, and to teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require manufacturers to calculate and report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under governmental healthcare programs.
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state laws and regulations, such as state anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states

regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. In addition, commercialization of any drug product outside the U.S. will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws in the future. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the company's business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found noncompliant with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights those actions, our business may be impaired.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws, and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While

existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, a smaller number of states have passed or are considering laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Additionally, to the extent we collect personal information from individuals outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data privacy and security laws, such as the European Union's General Data Protection Regulation 2016/679 (or EU GDPR) and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (or UK GDPR). Foreign privacy and data security laws impose significant and complex compliance obligations on entities that are subject to those laws, as more fully discussed in the section titled "*Risk Factors*".

Current and Future U.S. Healthcare Reform Legislation

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new and innovative technologies, such as pharmaceutical products like BCA101. In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell products profitably.

By way of example, the U.S. and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created the Medicare Part D coverage gap discount program, in which manufacturers agree to provide 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price for any approved products.

Since its enactment, there have been, and continue to be, numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and there could be additional amendments to the ACA in the future. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the ACA would have on our business.

Additionally, there have been several U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The IRA includes several provisions that may impact pharmaceutical companies to varying degrees, including provisions

that create a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries; impose new manufacturer financial liability on all drugs in Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D pricing caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for drug prices that increase faster than inflation; and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The full impact of the IRA on our business and the pharmaceutical and healthcare industry in general is not yet known.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Employees and Human Capital Resources

As of May 31, 2024, we had 27 full-time employees and 28 consultants. Within our workforce, 16 employees are engaged in research and development and 11 are engaged in business development, finance, legal, and general management and administration. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters is located in Boston, Massachusetts, where we lease and occupy 4,617 square feet of office and laboratory space. The current term of our Boston lease expires on February 28, 2026 with an option to continue thereafter on a month to month basis unless terminated by either party upon written notice. We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers And Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of May 31, 2024.

| <u>Name</u> | <u>Age</u> | <u>Position</u> |
|---------------------------------|------------|--------------------------------------|
| Executive Officers: | | |
| Claire Mazumdar, Ph.D., M.B.A. | 35 | Chief Executive Officer and Director |
| Ryan Cohlhepp, Pharm.D. | 47 | President, Chief Operating Officer |
| Ivan Hyep, M.B.A. | 39 | Chief Financial Officer |
| David Raben, M.D. | 60 | Chief Medical Officer |
| Lara Meisner, J.D. | 52 | Chief Legal Officer |
| Non-Executive Directors: | | |
| Nils Lonberg, Ph.D. | 68 | Chairman of the Board |
| Carolyn Ng, Ph.D. | 40 | Director |
| Vijay Kuchroo, D.V.M., Ph.D. | 68 | Director |
| Kiran Mazumdar-Shaw | 71 | Director |
| Heath Lukatch, Ph.D. | 57 | Director |
| Jake Simson, Ph.D. | 38 | Director |
| Ketan Patel, M.D., M.B.A. | 48 | Director |
| Kate Haviland, M.B.A. | 48 | Director |
| Scott Robertson, M.B.A. | 44 | Director |

Executive Officers

Claire Mazumdar, Ph.D., M.B.A., has served as our Chief Executive Officer and as a member of our board of directors since January 2020. Prior to Bicara, Dr. Mazumdar was Head of Business Development and Corporate Strategy at Rheos Medicines, Inc. a biopharmaceutical company, from August 2017 to December 2019, which culminated in a large multi-target discovery partnership with Roche. Previously, Dr. Mazumdar as an investment professional at Third Rock Ventures, LLC, or Third Rock, a life sciences venture capital firm, from July 2017 to July 2019. Dr. Mazumdar received a BS in Biological Engineering from Massachusetts Institute of Technology, a Ph.D. in Cancer Biology from Stanford School of Medicine, and an M.B.A. from Stanford Graduate School of Business. Dr. Mazumdar is the niece of Kiran Mazumdar-Shaw, a member of our board of directors. We believe Dr. Mazumdar's senior management experience in the biopharmaceutical industry make her well qualified to serve on our board of directors.

Ryan Cohlhepp, Pharm.D., has served as our President and Chief Operating Officer since October 2020, and served as a member of our board of directors from December 2020 to March 2023. Prior to Bicara, Dr. Cohlhepp was Senior Vice President R&D Strategy and Operations at Rheos Medicines, Inc., a biopharmaceutical company, from March 2018 to October 2020. Dr. Cohlhepp received a Pharm.D. from Purdue University.

Ivan Hyep, M.B.A., has served as our Chief Financial Officer since March 2021. Prior to joining Bicara Therapeutics, Mr. Hyep was the Director of Finance of MOMA Therapeutics, Inc., a biotechnology company, from July 2019 to March 2021. Previously, Mr. Hyep as an investment professional at Third Rock, a life sciences venture capital firm, from January 2016 to March 2021. Previously, Mr. Hyep was a Financing Manager at Bain

Capital, LP, a private investment firm, from July 2006 to January 2016. Mr. Hyep holds a BS in Finance from Bentley University and received his M.B.A. from Boston University.

David Raben, M.D., has served as our Chief Medical Officer since July 2023, having consulted for us from May 2023 to July 2023. Previously, Dr. Raben was Vice President of late-stage product development at Amgen Inc., a biotechnology company, from November 2021 to May 2023, where he led the recently FDA-approved Tarlatamab program for SCLC. Before that, he was Vice President of late-stage product development for lung, skin, head and neck cancer (HNC) at Genentech, Inc., a biotechnology company, from September 2019 to June 2021. He also served as a Professor of Radiation Oncology at the University of Colorado Health from May 1998 to September 2019. Dr. Raben is a board-certified radiation oncologist with a career focused on investigating novel biologic strategies against growth factor signaling and immunosuppression for patients advanced lung and HNC. He earned a BA in Psychology from Duke University in 1985, an M.D. from the Bowman Gray School of Medicine at Wake Forest University in 1990 and completed his residency at the Johns Hopkins Hospital in 1994.

Lara S. Meisner, J.D., has served as our Chief Legal Officer since November 2023 and Corporate Secretary since December 2023. Prior to joining Bicara, Ms. Meisner served as the Chief Legal Officer, Compliance Officer, and Corporate Secretary at Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company, from December 2020 to November 2023. From February 2017 to November 2020, Ms. Meisner held roles of increasing responsibility at Catabasis Pharmaceuticals, Inc. (now Astria Therapeutics, Inc. (NASDAQ: ATXS)), a biopharmaceutical company, most recently as the VP, Legal, and Corporate Secretary. Ms. Meisner received her J.D. from Temple University Beasley School of Law and her BA in Spanish and Communications from the University of Michigan.

Non-executive Directors

Nils Lonberg, Ph.D., has served as a member of our board of directors since April 2019 and Chairperson of our board of directors since December 2023. Dr. Lonberg currently serves as an Executive in Residence at Canaan Partners, a venture capital firm, where he has been employed since May 2019 and where he focuses on investments in life science companies. Prior to Canaan Partners, Dr. Lonberg served as Vice President, Oncology Discovery Biology, at Bristol-Myers Squibb Co., a biopharmaceutical company, where he led drug discovery efforts for both targeted and immunooncology agents, from September 2009 to April 2019. Dr. Lonberg also serves on the boards of directors of various private companies. Dr. Lonberg received his Ph.D. in Biochemistry and Molecular Biology from Harvard University. He was a postdoctoral fellow at Memorial Sloan Kettering Cancer Center and was elected to the National Academy of Engineering in 2015. We believe Dr. Lonberg's extensive executive, managerial and business experience with life sciences companies qualifies him to serve on our board of directors.

Carolyn Ng, Ph.D., has served as a member of our board of directors since December 2023. Dr. Ng currently serves as is a Partner and Managing Director at TPG Life Sciences Innovations, or TPG, a global investment firm, based in San Francisco, where she leads investments into transformative companies in different therapeutic areas since October 2021. Prior to joining TPG, Dr. Ng was a Managing Director at Vertex Ventures HC, a global healthcare and life sciences venture fund, where she joined in February 2015 and was promoted through various roles to be the co-Head of the investment team from June 2017 to September 2021. Dr. Ng currently serves on the board of directors of numerous private life sciences companies and previously served on the board of directors of several public companies, including Bicycle Therapeutics PLC (NASDAQ: BCYC), a biotechnology company, from June 2017 until August 2020, and Boundless Bio, Inc. (NASDAQ: BOLD), a clinical-stage oncology company, from June 2019 to September 2021. Dr. Ng holds a PhD in Cancer Molecular Biology from the National University of Singapore, where she was the recipient of the prestigious NGS, Integrative Sciences and Technology, PhD scholarship and holds a B.S. degree in Pharmacy with first class honors from the National University of Singapore. We believe Dr. Ng's extensive experience as an investor in and a member of the board of directors of numerous life sciences companies qualifies her to serve on our board of directors.

Vijay Kuchroo, D.V.M., Ph.D., has served as a member of our board of directors since December 2018 and was previously the Chairperson of our board of directors until December 2023. Dr. Kuchroo currently serves as a

the Samuel L. Wasserstrom Professor of Neurology at Harvard Medical School, an academic institution, since May 2005. Dr. Kuchroo has also been serving as a Director of the Gene Lay Institute of Immunology and Inflammation, a research institute, since June 2023. Dr. Kuchroo also serves on the boards of directors of Syngene International Ltd. (XNSE: SYNGENE), a life sciences company, since March 2017. Dr. Kuchroo received his BVSc at the College of Veterinary Medicine at Haryana Agricultural University in Hisar, India. Additionally, he received his Ph.D. at Department of Pathology and Public Health at University of Queensland. We believe Dr. Kuchroo's strong scientific and academic background and business experience with life sciences companies qualifies him to serve on our board of directors.

Kiran Mazumdar-Shaw has served as a member of our board of directors since December 2018. Ms. Mazumdar-Shaw founded Biocon Limited, an innovation-led global biopharmaceuticals company, in 1978 and has served as the Executive Chairperson since November 1978. Additionally, Ms. Mazumdar-Shaw has served as the Executive Chairperson of Biocon Biologics limited, a unique, fully integrated, global biosimilars company since January 2021. She is also serving as the Non-Executive Chairperson of Syngene International Limited, an innovation-led contract research, development and manufacturing organization since April 2020. Ms. Mazumdar-Shaw also serves on the boards of directors of various private companies, educational institutions and holds key positions in certain governmental bodies. Ms. Mazumdar-Shaw holds a B.Sc Honours degree in Zoology from Central College, Bangalore University and Post-Graduate in Malting and Brewing from Ballarat College, Melbourne University. She also has many honorary degrees from several renowned international universities. Ms. Mazumdar-Shaw is the aunt of our Chief Executive Officer Dr. Claire Mazumdar. We believe Ms. Mazumdar-Shaw's prolific experience as a pioneering biotech entrepreneur and healthcare visionary qualifies her to serve on our board of directors.

Heath S. Lukatch, Ph.D. has served as a member of our board of directors since August 2023. Since March 2020, Dr. Lukatch has served as Founder and Managing Partner of Red Tree Venture Capital, a privately held life sciences venture capital firm. Prior to founding Red Tree Venture Capital, from May 2015 to March 2020, Dr. Lukatch worked at TPG, where he was Partner, Managing Director and Life Sciences Investment Team Leader in TPG's Biotech, Growth and RISE platforms. In April 2006, Dr. Lukatch co-founded Novo Ventures (US) Inc.'s San Francisco office, a venture capital firm, where he was a Partner through April 2015. Dr. Lukatch is currently a member of the board of directors Vaxcyte, Inc. (NASDAQ: PCVX), a biotechnology company, since May 2018 and also serves on the boards of directors of various private companies. Previously, Dr. Lukatch served on the board of Cargo Therapeutics, Inc. (NASDAQ: CRGX), a biotechnology company, from January 2021 to November 2023, Satsuma Pharmaceuticals, Inc. (NASDAQ: STSA), a pharmaceutical company, from December 2016 to June 2023, Inogen, Inc. (NASDAQ: INGN), a medical technology company, from December 2006 to March 2022, and Flexion Therapeutics, Inc. (NASDAQ: FLXN), a biopharmaceutical company from December 2012 to November 2021, when it was acquired by Pacira BioSciences, Inc., and several other private companies. Dr. Lukatch received his Ph.D. in Neuroscience from Stanford University and his B.A. in Biochemistry from the University of California at Berkeley. We believe Dr. Lukatch is qualified to serve on our board of directors due to his educational background, his experience serving as a director for several private and public biopharmaceutical and healthcare companies and his experience in the life sciences investment industry.

Jake Simson, Ph.D., has served as a member of our board of directors since March 2023. Since December 2020, Dr. Simson has served as a Partner of RA Capital Management, L.P., a life sciences investment advisor. Dr. Simson previously served as an associate, analyst and principal at RA Capital Management, L.P. from July 2013 to December 2020. Dr. Simson serves as a member of the board of directors of Tyra Biosciences Inc, a public biotechnology company (NASDAQ GS: TYRA) and Janux Therapeutics, Inc, a public biopharmaceutical company (NASDAQ: JANX). Dr. Simson also served on the board of directors of DICE Therapeutics, Inc., a biotechnology company (NASDAQ: DICE) or DICE, from December 2020 until it was acquired by Eli Lilly and Company in August. Dr. Simson also serves on the boards of directors of various private companies. Dr. Simson received his Ph.D. in Biomedical Engineering from Johns Hopkins University and his S.B. in Materials Science and Engineering from Massachusetts Institute of Technology. We believe Dr. Simson is qualified to serve on our

board of directors due to his experience serving as a director for several private and public life science companies and his experience in the life sciences investment industry.

Ketan Patel, M.D., has served as a member of our board of directors since March 2023. Dr. Patel joined F-Prime Capital, a global venture capital firm, in August 2007 and currently holds the title of Managing Partner. Dr. Patel serves on the boards of directors of various private companies, such as ABK Biomedical, Inc., a medical device company, Comanche Biopharma Corp., a biopharmaceutical company, and Avalyn Pharmaceuticals, Inc., a biopharmaceutical company. Before joining F-Prime, Dr. Patel was an engagement manager in the corporate consulting division of Leerink Swann & Co., Inc., an investment bank. While at Leerink, he advised biopharmaceutical and medical device companies on brand strategy, clinical development plans, and business development activities. Dr. Patel served as a physician at the VA Boston Healthcare System and at Weill Cornell Medical Center-New York Presbyterian Hospital and Memorial-Sloan Kettering Cancer Center where he completed his internal medicine training. Dr. Patel received his M.D. and M.B.A. from Tufts University School of Medicine and his BS in biology and economics with highest honors at Rutgers University. We believe Dr. Patel is qualified to serve on our board of directors due to his experience serving as a director for several private life science companies and his experience in the life sciences investment industry.

Kate Haviland, M.B.A., has served as a member of our board of directors since September 2023. Since April 2022, Ms. Haviland has served as the President and Chief Executive Officer of Blueprint Medicines Corporation (NASDAQ: BPMC), a public biopharmaceutical company, and previously served as the Chief Operating Officer from January 2019 to April 2022, and as the Chief Business Officer from January 2016 to January 2019. Prior to joining Blueprint, Ms. Haviland served as vice president, rare diseases and oncology program leadership at Idera Pharmaceuticals, Inc. (acquired by Acergen, Inc.), a biopharmaceutical company, from April 2014 to December 2015, as head of commercial development at Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a public biopharmaceutical and drug development company, from June 2012 to April 2014, as executive director of commercial development at PTC Therapeutics, Inc. (NASDAQ: PTCT), a public biopharmaceutical company, from March 2007 to June 2012, and roles in corporate development and project management at Genzyme, Inc. (acquired by Sanofi, Inc. (NASDAQ: SNY), a global healthcare company) from July 2005 to April 2007. Ms. Haviland currently serves on the board of directors of Fulcrum Therapeutics, Inc. (NASDAQ: FULC), a public biopharmaceutical company. Ms. Haviland holds a B.A. from Wesleyan University with a double major in Molecular Biology/Biochemistry and Economics and an M.B.A. from Harvard Business School. We believe Ms. Haviland is qualified to serve on our board of directors because she is a biotech President and Chief Executive Officer and experienced as a public company board member in the life science industry.

Scott Robertson, M.B.A., has served as a member of our board of directors since September 2023. Mr. Robertson currently serves as the Chief Financial Officer and Chief Business Officer of Star Therapeutics LLC, a biotechnology company, since January 2024. Mr. Robertson also served as the Chief Financial Officer and Chief Business Officer of DICE from July 2021 to December 2023, the Chief Financial Officer from December 2017 to July 2021, and as the Vice President, Business Development & Strategic Planning from April 2016 to December 2017, prior to acquisition by Eli Lilly and Company in August 2023. In addition, he currently serves as a Lecturer at the Haas School of Business at the University of California, Berkeley and previously served as a member of the board of directors of Hexima Limited (ASX:HXL), a biotechnology company, from December 2018 to September 2023. Mr. Robertson received his B.S. in Business Administration from the University of Southern California and his M.B.A. from the Haas School of Business at the University of California, Berkeley. We believe Mr. Robertson's extensive executive and business experience with life sciences companies qualifies him to serve on our board of directors. Composition of our board of directors.

Our current board consists of ten (10) members, each of whom are members pursuant to the board composition provisions of our second amended and restated certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our

directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our fifth amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering and amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director independence

Our board of directors has determined that all members of the board of directors, except Claire Mazumdar Ph.D., are independent directors, including for purposes of the rules of the Nasdaq Global Market and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the Nasdaq Global Market and the rules and regulations of the SEC. Dr. Mazumdar is the niece of Ms. Mazumdar-Shaw, otherwise, there are no family relationships among any of our directors or executive officers. Dr. Mazumdar is not an independent director under these rules because she is the Chief Executive Officer of the Company.

Staggered board

In accordance with the terms of our fifth amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering and our amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years _____ for Class I directors, _____ for Class II directors and _____ for Class III directors.

- Our Class I directors will be _____ ;
- Our Class II directors will be _____ ; and
- Our Class III directors will be _____ .

Our fifth amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering and amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board leadership structure

Currently, the role of chairperson of the board of directors is separated from the role of Chief Executive Officer. Our Chief Executive Officer is responsible for recommending strategic decisions and capital allocation to the board of directors and to ensure the execution of the recommended plans. The chairperson of the board of directors is responsible for leading the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to her position in the current business environment, as well as the commitment required to serve as our chairperson, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines will not require that our chairperson and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Role of the board in risk oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including the risks relating to our financial condition, development and commercialization activities, operations, strategic direction, and intellectual property as more fully discussed in the section titled "*Risk Factors*" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors that will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The board of directors may also establish other committees from time to time to assist the Company and the board of directors. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations, if applicable. Upon our listing on Nasdaq, each committee's charter will be available on our website at www.bicara.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

Audit committee

serve on the audit committee, which is chaired by . Our board of directors has determined that each are "independent" for audit committee purposes as that term is defined by the rules of the SEC and Nasdaq, and that each has sufficient knowledge in financial and auditing matters to serve on the audit committee.

Our board of directors has designated _____ as an “audit committee financial expert,” as defined under the applicable rules of the SEC. The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee’s review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- reviewing and discussing with management and our board of directors our cybersecurity risks, including information security and technology risks;
- reviewing and discussing with management and our board of directors our cybersecurity risks, including information security and technology risks;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions;
- reviewing quarterly earnings releases; and
- reviewing our major risk exposures, including financial, operational, cybersecurity, competition, legal and regulatory exposures.

Compensation committee

_____ serve on the compensation committee, which is chaired by _____. Our board of directors has determined that each member of the compensation committee is “independent” as defined in the applicable Nasdaq rules. The compensation committee’s responsibilities include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation: (i) recommending to the board of directors the cash compensation of our Chief Executive Officer, and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;

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- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors; and
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

Nominating and corporate governance committee

serve on the nominating and corporate governance committee, which is chaired by . Our board of directors has determined that each member of the nominating and corporate governance committee is “independent” as defined in the applicable Nasdaq rules. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- reviewing and recommending to the board of directors appropriate corporate governance guidelines; and
- overseeing the evaluation of our board of directors.

Compensation committee interlocks and insider participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Compensation recovery

In connection with this offering, we intend to adopt a compensation recovery policy that applies to our officers. Under the Sarbanes-Oxley Act, in the event of misconduct that results in a financial restatement that would have reduced a previously paid incentive amount, we can recoup those improper payments from our chief executive officer and chief financial officer. The SEC also recently adopted rules which direct national stock exchanges to require listed companies to implement policies intended to recoup bonuses paid to executives if the company is found to have misstated its financial results.

Corporate governance

Prior to the effectiveness of the registration statement of which this prospectus is a part, we will adopt a written code of business conduct and ethics that applies to our directors, officers, and employees, including our

principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of this code will be posted on the Corporate Governance section of our website, which is located at www.bicara.com. The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Limitations on liability and indemnification matters

As permitted by Delaware law, provisions in our fifth amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and amended and restated bylaws, which became effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of officers and directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, an officer or director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, an officer or director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as an officer or director, except for liability for:

- any breach of the officer or director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our directors, unlawful payments of dividends or unlawful stock repurchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law, or DGCL;
- for our officers, any derivative action by or in the right of the corporation;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter an officer or director's liability under other laws, such as the federal securities laws or other state or federal laws. Our fifth amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws, which will become effective upon the effectiveness of this registration statement will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our fifth amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our fifth amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plans would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

EXECUTIVE COMPENSATION

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Exchange Act. The compensation provided to our named executive officers, or NEOs, for the year ended December 31, 2023 is detailed in the “2023 Summary Compensation Table” and accompanying footnotes and narrative that follow. Our NEOs for the year ended December 31, 2023, which consist of our Chief Executive Officer and the two most highly compensated executive officers (other than our Chief Executive Officer) who were serving as our executive officers on December 31, 2023, are:

- Claire Mazumdar, Ph.D., M.B.A., our Chief Executive Officer;
- Ryan Cohlhepp, Pharm.D., our President and Chief Operating Officer; and
- Ivan Hyep, M.B.A., our Chief Financial Officer.

2023 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to our NEOs for services rendered to us in all capacities during the fiscal year ended December 31, 2023.

| Name and Principal Position | Year | Salary(\$) | Bonus(\$)(1) | Option Awards(\$)(2) | Non-Equity Incentive Plan Compensation (\$)(3) | Total(\$) |
|---|------|------------|--------------|----------------------|--|-----------|
| Claire Mazumdar, Ph.D., M.B.A. <i>Chief Executive Officer</i> | 2023 | 450,000 | 180,000 | 3,893,323 | 20,000 | 4,543,323 |
| Ryan Cohlhepp, Pharm.D. <i>President and Chief Operating Officer</i> | 2023 | 450,000 | 190,000 | 2,498,786 | 20,000 | 3,158,786 |
| Ivan Hyep, M.B.A. <i>Chief Financial Officer</i> | 2023 | 350,000 | 247,500 | 1,883,243 | — | 2,480,743 |

- (1) The amounts reported include annual bonuses earned by our NEOs during the fiscal year ended December 31, 2023 (\$180,000 for Dr. Mazumdar, \$180,000 for Dr. Cohlhepp, and \$122,500 for Mr. Hyep). In the case of Dr. Cohlhepp, the amount reported also includes referral bonuses in an aggregate amount of \$10,000 and, in the case of Mr. Hyep, the amount reported also includes a retention bonus in an amount of \$125,000.
- (2) The amounts reported represent the aggregate grant date fair value of stock options awarded to our NEOs during the fiscal year ended December 31, 2023, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, disregarding estimated forfeitures related to service-based vesting. For a description of the assumptions used in determining these values, see Note 11 of our consolidated financial statements included elsewhere in this prospectus. The amount reported in this column reflects the accounting cost for the stock options and does not correspond to the actual economic value that may be received by our NEOs upon the exercise of the stock options or any sale of the underlying shares.
- (3) The amounts reported represent milestone bonuses earned in connection with our Series B preferred stock financing, as described below under “2023 Cash Incentive Compensation”.

Narrative to the 2023 Summary Compensation Table

2023 Base Salaries

Our NEOs each receive a base salary to compensate them for services rendered to us. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee of our board of directors (the "compensation committee"), and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For the fiscal year ended December 31, 2023, the annual base salaries for Dr. Mazumdar, Dr. Cohlhepp, and Mr. Hyep were \$450,000, \$450,000, and \$350,000, respectively. Effective as of January 1, 2024, the annual base salaries for Dr. Mazumdar, Dr. Cohlhepp, and Mr. Hyep were increased to \$500,000, \$500,000, and \$425,000, respectively, reflecting merit-based increases.

2023 Cash Incentive Compensation

For the fiscal year ended December 31, 2023, each of our NEOs was eligible to earn an annual bonus based on the Company's achievement of certain non-formulaic performance objectives, as determined by our board of directors. The target annual bonus for 2023 for Dr. Mazumdar, Dr. Cohlhepp, and Mr. Hyep were 40%, 40%, and 35%, respectively, of the NEO's applicable annual base salary. The annual bonus earned by each NEO with respect to the fiscal year ended December 31, 2023 was \$180,000 for each of Dr. Mazumdar and Dr. Cohlhepp and \$122,500 for Mr. Hyep. Effective as of January 1, 2024, the target annual bonus for each of Dr. Mazumdar, Dr. Cohlhepp, and Mr. Hyep was increased to 45%, 45% and 40%, respectively, of the NEO's annual base salary, reflecting merit-based increases.

On September 26, 2021, we entered into a retention bonus letter agreement with Mr. Hyep (the "Hyep Retention Letter") that provides for a retention bonus in the aggregate amount of \$500,000, payable in four equal installments on each of June 1, 2022, 2023, 2024, and 2025, subject to Mr. Hyep's continued service with us through the applicable payment date. The \$125,000 retention bonus earned by Mr. Hyep during the fiscal year ended December 31, 2023 is reported under the "Bonus" column in the "2023 Summary Compensation Table" above.

In addition, during the fiscal year ended December 31, 2023, Dr. Cohlhepp received two referral bonuses in an aggregate amount equal to \$10,000, as reported under the "Bonus" column in the "2023 Summary Compensation Table" above. Under the Company's referral bonus program, employees are eligible to receive a referral bonus in the amount of \$5,000 for each new hire referred to the Company, which amount is payable on the six-month anniversary of the referred employee's start date with the Company.

Furthermore, Dr. Mazumdar and Dr. Cohlhepp each earned \$20,000 in milestone bonuses in connection with the Company's completion of its Series B preferred stock financing and the Company's achievement of certain Series B preferred stock financing goals, as reported under the "Non-Equity Incentive Plan Compensation" column in the "2023 Summary Compensation Table" above.

Equity-based Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture, and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period.

Accordingly, our board of directors periodically reviews the equity incentive compensation of our executive officers and may grant equity incentive awards to them from time to time. During the fiscal year ended December 31, 2023, we granted option awards to our NEOs under our 2019 Plan, as described in more detail in the “*Outstanding Equity Awards at 2023 Fiscal Year-End*” table below.

Perquisites or Personal Benefits

Perquisites and other personal benefits are not a significant component of our executive compensation program. Accordingly, we do not provide perquisites or personal benefits to our NEOs.

401(k) Plan

We currently maintain a tax-qualified 401(k) retirement savings plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms as other full-time employees. Our 401(k) plan is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We did not provide any matching or discretionary contributions under the 401(k) plan during the fiscal year ended December 31, 2023. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our NEOs, in accordance with our compensation policies. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our NEOs.

Executive Employment Arrangements

Prior employment arrangements in place during the 2023 fiscal year

Claire Mazumdar, Ph.D., M.B.A.

Effective as of January 6, 2020, the Company entered into an employment agreement with Dr. Mazumdar, as amended by the First Amendment to Employment Agreement effective as of November 3, 2023, for the position of Chief Executive Officer, or the Prior Mazumdar Employment Agreement. The Prior Mazumdar Employment Agreement provided for Dr. Mazumdar’s at-will employment, and an initial annual base salary and initial target annual incentive compensation amount, each of which has subsequently been increased as described above under “*2023 Base Salaries*” and “*2023 Cash Incentive Compensation*”. The Prior Mazumdar Employment Agreement also provided for an initial grant of a number of shares of restricted stock. Under the terms of the Prior Mazumdar Employment Agreement, Dr. Mazumdar was eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans.

In addition, the Prior Mazumdar Employment Agreement provided that in the event that Dr. Mazumdar’s employment was terminated by the Company without “cause” or she resigned for “good reason” (as each term was defined in the Prior Mazumdar Employment Agreement), subject to Dr. Mazumdar’s execution and the effectiveness of a separation agreement, including a general release of claims in the Company’s favor, she would have been entitled to receive (i) base salary continuation for 12 months following termination, (ii) subject to the Company’s attainment of the applicable performance goals for the applicable fiscal year, a pro-rated portion of her target cash incentive compensation for the year of termination, (iii) subject to Dr. Mazumdar’s copayment of premium amounts at the applicable active employees’ rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that the Company would have paid to provide health insurance to Dr. Mazumdar had she remained employed with the Company until the earliest of (A) 12 months following termination, (B) Dr. Mazumdar’s eligibility for group medical plan benefits under any other employer’s group medical plan, or (C) the end of Dr. Mazumdar’s COBRA health continuation period, and (iv) if such termination had occurred within 12 months immediately following a “sale event” (as such term was defined in the Prior Mazumdar Employment Agreement), accelerated vesting of all time-based stock options held by Dr. Mazumdar.

Pursuant to the Prior Mazumdar Employment Agreement, in the event that Dr. Mazumdar's employment terminated for any reason, she would have been entitled to receive any earned but unpaid annual bonus for the year prior to the year of termination. Pursuant to the Prior Mazumdar Employment Agreement, in the event that Dr. Mazumdar's employment terminated due to her death or disability, she would have been entitled to receive a pro-rated portion of her target cash incentive compensation for the year of termination, subject to the Company's attainment of the applicable performance goals for such year.

Dr. Mazumdar also entered into a standard form agreement with respect to confidential information, intellectual property assignment and non-competition and non-solicitation restrictions.

Ryan Cohlhepp, Pharm.D.

Effective as of October 19, 2020, the Company entered into an employment agreement with Dr. Cohlhepp, as amended by the First Amendment to Employment Agreement effective as of November 3, 2023, for the position of President and Chief Operating Officer, or the Prior Cohlhepp Employment Agreement. The Prior Cohlhepp Employment Agreement provided for Dr. Cohlhepp's at-will employment, and an initial annual base salary and initial target annual incentive compensation amount, each of which has subsequently been increased as described above under "2023 Base Salaries" and "2023 Cash Incentive Compensation". The Prior Cohlhepp Employment Agreement also provided for an initial grant of a number of shares of restricted stock. Under the Prior Cohlhepp Employment Agreement, Dr. Cohlhepp was eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans.

In addition, the Prior Cohlhepp Employment Agreement provided that in the event that Dr. Cohlhepp's employment was terminated by the Company without "cause" or he resigned for "good reason" (as each term was defined in the Prior Cohlhepp Employment Agreement), subject to Dr. Cohlhepp's execution and the effectiveness of a separation agreement, including a general release of claims in the Company's favor, he would have been entitled to receive (i) base salary continuation for 12 months following termination, (ii) subject to the Company's attainment of the applicable performance goals for the applicable fiscal year, a pro-rated portion of his target cash incentive compensation for the year of termination, (iii) subject to Dr. Cohlhepp's copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that the Company would have paid to provide health insurance to Dr. Cohlhepp had he remained employed with the Company until the earliest of (A) 12 months following termination, (B) Dr. Cohlhepp's eligibility for group medical plan benefits under any other employer's group medical plan, or (C) the end of Dr. Cohlhepp's COBRA health continuation period, and (iv) if such termination had occurred within 12 months immediately following a "sale event" (as such term was defined in the Prior Cohlhepp Employment Agreement), accelerated vesting of all time-based stock options held by Dr. Cohlhepp.

Pursuant to the Prior Cohlhepp Employment Agreement, in the event that Dr. Cohlhepp's employment terminated for any reason, he would have been entitled to receive any earned but unpaid annual bonus for the year prior to the year of termination. Pursuant to the Prior Cohlhepp Employment Arrangement, in the event that Dr. Cohlhepp's employment terminated due to his death or disability, he would have been entitled to receive a pro-rated portion of his target cash incentive compensation for the year of termination, subject to the Company's attainment of the applicable performance goals for such year.

Dr. Cohlhepp also entered into a standard form agreement with respect to confidential information, intellectual property assignment and non-competition and non-solicitation restrictions.

Ivan Hyep, M.B.A.

On February 8, 2021, the Company entered into an offer letter with Mr. Hyep, as amended by the First Amendment to Employment Agreement effective as of November 3, 2023 for the position of Chief Financial

Officer, or the Prior Hyep Employment Arrangement. The Prior Hyep Employment Arrangement provided for Mr. Hyep's at-will employment, and an initial annual base salary and initial target annual incentive compensation amount, each of which has subsequently been increased as described above under "2023 Base Salaries" and "2023 Cash Incentive Compensation". The Prior Hyep Employment Arrangement also provided for an initial grant of a number of shares of restricted stock or a stock option award. Under the Prior Hyep Employment Arrangement, Mr. Hyep was eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans.

In addition, the Prior Hyep Employment Arrangement provided that in the event that Mr. Hyep's employment was terminated by the Company without "cause" (as such term was defined in the Prior Hyep Employment Arrangement), subject to Mr. Hyep's signing and not revoking a separation agreement and release of claims in the Company's favor, he would have been entitled to receive (i) base salary continuation for 12 months following termination, and (ii) subject to Mr. Hyep's copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that the Company would have paid to provide health insurance to Mr. Hyep had he remained employed with the Company until the earliest of (A) 12 months following termination, (B) Mr. Hyep's eligibility for group medical plan benefits under any other employer's group medical plan, or (C) the end of Mr. Hyep's COBRA health continuation period.

Mr. Hyep also entered into a standard form agreement with respect to confidential information, intellectual property assignment and non-competition and non-solicitation restrictions.

Employment arrangements in place during the 2024 fiscal year

Effective as of March 1, 2024, the Company entered into amended and restated employment agreements with Dr. Mazumdar, Dr. Cohlhepp, and Mr. Hyep (collectively, the "Amended Employment Agreements"), that supersede in all respects all prior employment agreements, offer letters and severance agreements between Dr. Mazumdar, Dr. Cohlhepp, Mr. Hyep, respectively, and the Company, including the Prior Mazumdar Employment Agreement, the Prior Cohlhepp Employment Agreement, and the Prior Hyep Employment Arrangement, each as described above.

Under the Amended Employment Agreements, each of the NEOs continues to serve in their respective roles on an at-will basis. The Amended Employment Agreements provide for each NEO's base salary, which is subject to periodic review by our board of directors or the compensation committee, and a target annual cash incentive opportunity, with the actual amount of any annual cash bonus determined by our board of directors or the compensation committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time. Each NEO's current base salary and target annual cash incentive opportunity is described above under "2023 Base Salaries" and "2023 Cash Incentive Compensation". The NEOs are also eligible to participate in the Company's U.S. employee benefit plans available to employees, subject to the terms of those plans.

Pursuant to the Amended Employment Agreements, in the event that an NEO's employment is terminated by the Company without "cause" or the NEO resigns for "good reason", in either case outside of the one-year period following a "change in control" (as each such term is defined in the Amended Employment Agreements), subject to the applicable NEO signing a separation agreement and release of claims in the Company's favor and such separation agreement and release becoming fully effective no more than 60 days after the termination date, such NEO will be entitled to receive (i) base salary continuation for 12 months following termination, (ii) subject to the Company's attainment of the applicable pre-established performance goals for the year of termination, a pro-rated portion of such NEO's target cash incentive compensation for the year of termination, or Pro-Rata Bonus, and (iii) subject to the applicable NEO's copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that we would have paid to provide health insurance to such NEO had he or she remained

employed with the Company until the earliest of (A) 12 months following termination, (B) the applicable NEO's eligibility for group medical plan benefits under any other employer's group medical plan, or (C) the end of the applicable NEO's COBRA health continuation period.

Pursuant to the Amended Employment Agreements, in lieu of the payments and benefits described in the preceding sentence, in the event that the NEO's employment is terminated by the Company without cause or the NEO resigns for good reason, in either case within one year following a change in control, subject to the applicable NEO signing a separation agreement and release of claims in the Company's favor and such separation agreement and release becoming fully effective no more than 60 days after the termination date, such NEO will be entitled to receive (i) 12 months of such NEO's then-current annual base salary (or such NEO's annual base salary in effect immediately prior to the change in control, if higher), payable in a lump sum, (ii) a Pro-Rata Bonus, (iii) subject to the applicable NEO's copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that the Company would have paid to provide health insurance to such NEO had he or she remained employed with the Company until the earliest of (A) 12 months following termination, (B) the applicable NEO's eligibility for group medical plan benefits under any other employer's group medical plan, or (C) the end of the applicable NEO's COBRA health continuation period, and (iv) full accelerated vesting of 100% of all stock options and other stock-based awards subject solely to time-based vesting held by such NEO.

Pursuant to the Amended Employment Agreements, in the event that an NEO's employment is terminated for any reason, such NEO will be entitled to receive any earned but unpaid annual bonus for the year prior to the year of termination. In the event that an NEO's employment is terminated due to the NEO's death or disability, such NEO will also be entitled to receive a Pro-Rata Bonus.

Pursuant to the Amended Employment Agreements, if the payments and benefits payable to the applicable NEO in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the applicable NEO than if he or she had been paid the full amount of such payments and benefits, with such amount subject to the excise tax.

The standard form agreement with respect to confidential information, intellectual property assignment and non-competition and non-solicitation restrictions that the NEOs entered into before this offering remains in full force and effect.

Compensation Recovery Policy

In accordance with the requirements of the Dodd-Frank Act, final SEC rules, and applicable Nasdaq listing standards, our board of directors plans to adopt a compensation recovery policy, which will become effective upon the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The compensation recovery policy will provide that in the event we are required to prepare a restatement of financial statements due to material noncompliance with any financial reporting requirement under securities laws, we will seek to recover any incentive-based compensation that was based upon the attainment of a financial reporting measure and that was received by any current or former executive officer during the three-year period preceding the date that the restatement was required if such compensation exceeds the amount that the executive officer would have received based on the restated financial statements.

Outstanding Equity Awards at Fiscal 2023 Year-End

The following table sets forth information concerning outstanding equity awards held by the NEOs as of December 31, 2023.

| Name | Grant Date | Vesting Commencement Date | Option Awards(1) | | | Stock Awards(1) | | |
|-----------------------------------|------------|---------------------------|---|---|----------------------------|------------------------|---|---|
| | | | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested (\$)(2) |
| Claire Mazumdar, Ph.D., M.B.A. | 9/15/2020 | 2/25/2020 | — | — | — | — | 9,630 ⁽³⁾ | 5,682 |
| | 9/15/2020 | 1/6/2020 | — | — | — | — | 112,350 ⁽⁴⁾ | 66,287 |
| | 11/19/2021 | 11/8/2021 | 449,400 ⁽³⁾ | 449,400 ⁽³⁾ | 0.44 | 11/19/2031 | | |
| | 11/19/2021 | 11/8/2021 | 38,520 ⁽³⁾ | 38,520 ⁽³⁾ | 0.44 | 11/19/2031 | | |
| | 10/4/2022 | 10/4/2022 | 150,000 ⁽³⁾ | 450,000 ⁽³⁾ | 0.48 | 10/4/2032 | | |
| | 4/5/2023 | 4/5/2023 | 212,500 ⁽³⁾ | 1,487,500 ⁽³⁾ | 0.41 | 4/5/2033 | | |
| | 8/8/2023 | 8/8/2023 | 215,313 ⁽³⁾ | 3,229,687 ⁽³⁾ | 0.41 | 8/8/2033 | | |
| | 12/14/2023 | 12/14/2023 | — | 5,500,000 ⁽³⁾ | 0.59 | 12/14/2033 | | |
| Ryan Cohlhepp, Pharm.D. | 9/28/2020 | 10/19/2020 | — | — | — | — | 218,280 ⁽⁴⁾ | 128,785 |
| | 9/28/2020 | 10/19/2020 | — | — | — | — | 38,520 ⁽³⁾ | 22,727 |
| | 11/19/2021 | 11/8/2021 | 218,280 ⁽³⁾ | 218,280 ⁽³⁾ | 0.44 | 11/19/2031 | | |
| | 11/19/2021 | 11/8/2021 | 38,520 ⁽³⁾ | 38,520 ⁽³⁾ | 0.44 | 11/19/2031 | | |
| | 10/4/2022 | 10/4/2022 | 150,000 ⁽³⁾ | 450,000 ⁽³⁾ | 0.48 | 10/4/2032 | | |
| | 4/5/2023 | 4/5/2023 | 137,500 ⁽³⁾ | 962,500 ⁽³⁾ | 0.41 | 4/5/2033 | | |
| | 8/8/2023 | 8/8/2023 | 140,313 ⁽³⁾ | 2,104,687 ⁽³⁾ | 0.41 | 8/8/2033 | | |
| | 12/14/2023 | 12/14/2023 | — | 3,500,000 ⁽³⁾ | 0.59 | 12/14/2033 | | |
| Ivan Hyep, M.B.A. | 2/22/2021 | 3/15/2021 | — | — | — | — | 192,600 ⁽⁴⁾ | 113,634 |
| | 11/19/2021 | 11/8/2021 | 154,080 ⁽³⁾ | 154,080 ⁽³⁾ | 0.44 | 11/19/2031 | | |
| | 10/4/2022 | 10/4/2022 | 150,000 ⁽³⁾ | 450,000 ⁽³⁾ | 0.48 | 10/4/2032 | | |
| | 4/5/2023 | 4/5/2023 | 103,750 ⁽³⁾ | 726,250 ⁽³⁾ | 0.41 | 4/5/2033 | | |
| | 8/8/2023 | 8/8/2023 | 109,063 ⁽³⁾ | 1,635,937 ⁽³⁾ | 0.41 | 8/8/2033 | | |
| | 12/14/2023 | 12/14/2023 | — | 2,600,000 ⁽³⁾ | 0.59 | 12/14/2033 | | |

- (1) Each equity award was granted pursuant to and is subject to the terms of the 2019 Plan (as described below).
- (2) This amount is based on the fair market value of a share of our common stock of \$0.59 as of December 31, 2023, as determined by our board of directors.
- (3) The shares underlying the stock option award or restricted stock award, as applicable, vest in 16 equal quarterly installments over a four-year period, commencing on the vesting commencement date, subject to the applicable NEO's continued employment through the applicable vesting date. The award is also subject to certain accelerated vesting rights as set forth in the applicable NEO's Amended Employment Agreement, as described above.
- (4) The shares underlying the stock option award or restricted stock award, as applicable, vest as follows: 25% of such shares vested on the first anniversary of the vesting commencement date, and the remaining 75% of the shares vest in 12 equal quarterly installments over the following three years, subject to the applicable NEO's continued employment through the applicable vesting date. The award is also subject to certain accelerated vesting rights as set forth in the applicable NEO's Amended Employment Agreement, as described above.

Employee Benefit and Equity Compensation Plans

2019 Stock Option and Grant Plan

The 2019 Plan was initially approved and adopted by our board of directors and stockholders on July 17, 2019 and has been subsequently amended from time to time thereafter to increase the number of shares reserved for issuance thereunder. Under the 2019 Plan, we have reserved an aggregate of 54,362,703 shares of our common stock for the issuance of stock options and other equity awards under the 2019 Plan. This number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization. As of December 31, 2023, options to purchase 44,837,663 shares of common stock and 436,290 shares of restricted stock were outstanding under the 2019 Plan. Our board of directors has determined not to make any further awards under the 2019 Plan following the closing of this offering, but all outstanding awards under the 2019 Plan will continue to be governed by their existing terms. The maximum number of shares that may be issued as incentive stock options under the 2019 Plan may not exceed 543,627,030 shares. In connection with this offering, we intend to adopt a new incentive equity plan under which we will grant equity-based awards following this offering, as described below under “*2024 Stock Option and Grant Plan*.” This summary is not a complete description of all provisions of the 2019 Plan and is qualified in its entirety by reference to the 2019 Plan, which will be filed as an exhibit to the registration statement of which this prospectus is part.

The shares of common stock underlying any awards that are forfeited, cancelled, reacquired by us prior to vesting, satisfied without the issuance of stock, or otherwise terminated (other than by exercise), or held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding under the 2019 Plan are added back to the shares of common stock available for issuance under the 2019 Plan (and, following the completion of this offering, will be added back to the shares of common stock available for issuance under the 2024 Plan (as defined below)).

Our board of directors has acted as administrator of the 2019 Plan. The administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, and to determine the specific terms and conditions of each award, subject to the provisions of the 2019 Plan. Persons eligible to participate in the 2019 Plan are those full or part-time officers, employees, non-employee directors, consultants, and key persons as selected from time to time by the administrator in its discretion.

The 2019 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by the administrator of the 2019 Plan but may not be less than 100% of the fair market value of our common stock on the date of grant, or in the case of an incentive stock option granted to a 10% owner, the exercise price shall not be less than 110% of the fair market value of our common stock on the date of grant. The term of each option is fixed by the 2019 Plan administrator and may not exceed ten years from the date of grant, or five years from the date of grant in the case of an incentive stock option granted to a 10% owner. The 2019 Plan administrator determines at what time or times each option may be exercised.

The 2019 Plan administrator may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include continued employment or other service relationship with us through a specified vesting period and/or the achievement of certain performance goals.

The 2019 Plan administrator may also grant shares of common stock that are free from any restrictions under the 2019 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

In the event of certain corporate transactions and events, including a reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split, or other similar change to the Company's capital stock, the 2019 Plan administrator shall make appropriate adjustments to the maximum number of shares reserved for issuance under the 2019 Plan, the number and kind of securities subject to outstanding awards under the 2019 Plan, and the repurchase or exercise price of any outstanding awards under the 2019 Plan.

Upon the effective time of a "sale event" (as defined in the 2019 Plan), all outstanding option awards granted under the 2019 Plan and the 2019 Plan shall terminate unless assumed or continued by a successor entity. In the event of such termination, individuals holding options will be permitted to exercise such options within a specified period of time prior to the sale event. In the event of a sale event, all unvested restricted stock awards and restricted stock units (other than those that become vested as a result of the sale event) will be forfeited unless assumed or continued by a successor entity. With respect to individuals holding restricted stock that is forfeited upon a sale event, such restricted stock shall be repurchased by the Company at a price per share equal to the original per share purchase price paid by the holder for such shares of restricted stock. In addition, in connection a sale event, we may make or provide for a cash payment to participants in exchange for the cancellation of their options (to the extent then vested and exercisable, including by reason of acceleration in connection with such sale event) or outstanding restricted stock or restricted stock units, in an amount equal to the difference between (a) the per share consideration in the sale event times the number of shares subject to such awards being cancelled and (b) the aggregate price paid, or exercise price, as applicable, if any, of the awards.

Our board of directors may amend or discontinue the 2019 Plan and the 2019 Plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under any outstanding award without the holder's consent. Certain amendments to the 2019 Plan require the approval of our stockholders. The 2019 Plan administrator may exercise its discretion to reduce the exercise price of outstanding stock options or to effect repricing through the cancellation of outstanding stock options and grant of replacement awards.

No awards may be granted under the 2019 Plan after the date that is ten years from the effective date of the 2019 Plan.

2024 Stock Option and Grant Plan

Our 2024 Stock Option and Grant Plan, or the 2024 Plan, was adopted by our board of directors on _____, approved by our stockholders on _____, and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2024 Plan will replace the 2019 Plan as our board of directors has determined not to make additional awards under the 2019 Plan following the closing of our initial public offering. However, the 2019 Plan will continue to govern outstanding equity awards granted thereunder. The 2024 Plan allows us to make equity-based and cash-based incentive awards to our officers, employees, directors and consultants. The following summary describes the material terms of the 2024 Plan. This summary is not a complete description of all provisions of the 2024 Plan and is qualified in its entirety by reference to the 2024 Plan, which will be filed as an exhibit to the registration statement to which this prospectus is a part.

We have initially reserved _____ shares of our common stock for the issuance of awards under the 2024 Plan, or the Initial Limit. The 2024 Plan provides that the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter during the term of the 2024 Plan, by _____ % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2024 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2024 Plan and the 2019 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2024 Plan.

The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2025 and on each January 1 thereafter by the lesser of the Annual Increase for such year or _____ shares of common stock.

The grant date fair value of all awards made under our 2024 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed \$ _____; provided, however, that such amount shall be \$ _____ for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2024 Plan will be administered by our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, and to determine the specific terms and conditions of each award, subject to the provisions of the 2024 Plan. Persons eligible to participate in the 2024 Plan will be those full or part-time officers, employees, non-employee directors, and consultants as selected from time to time by our compensation committee in its discretion.

The 2024 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to U.S. income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock options). Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights under the 2024 Plan subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right generally may not be less than 100% of the fair market value of our common stock on the date of grant unless the share appreciation right (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to U.S. income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2024 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2024 Plan to participants, subject to the achievement of certain performance goals.

The 2024 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2024 Plan, an acquirer or successor entity may assume, continue, or substitute outstanding awards under the 2024 Plan. To the extent that awards granted under the 2024 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award agreement, all awards with time-based vesting, conditions, or restrictions will become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the administrator’s discretion or to the extent specified in the relevant award agreement. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2024 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2024 Plan require the approval of our stockholders. The administrator of the 2024 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2024 Plan after the date that is 10 years from the effective date of the 2024 Plan. No awards under the 2024 Plan have been made prior to the date of this prospectus.

2024 Employee Stock Purchase Plan

Our 2024 Employee Stock Purchase Plan, or the ESPP, was approved by our board of directors on [redacted], approved by our stockholders on [redacted] 2024, and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. The ESPP is intended to have two components: a component intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code, or the 423 Component and a component that is not intended to qualify, or the Non-423 Component. Except as otherwise provided, the Non-423 Component will be operated and administered in the same manner as the 423 Component, except where prohibited by law. The following summary describes the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which will be filed as an exhibit to the registration statement to which this prospectus is a part.

The ESPP initially reserves and authorizes the issuance of up to a total of [redacted] shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2025 and each January 1 thereafter through January 1, 2034, by the least of (i) [redacted] shares of common stock, (ii) [redacted] % of the outstanding number of shares of common stock on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

All individuals classified as employees on the payroll records of the Company or a “designated company” (as defined in the ESPP) as of the first day of the applicable offering period, or the Offering Date, are eligible to participate in the ESPP; provided that the administrator of the ESPP may determine, in advance of any offering period, that employees are eligible only if, as of the Offering Date, they (a) are customarily employed by us or a designated company for more than 20 hours a week, (b) are customarily employed by us or a designated company for more than five months per calendar year, and/or (c) have completed at least _____ of employment (or other such period as determined by the administrator of the ESPP, provided such service requirement does not exceed two years of employment). However, any employee who owns, or as a result of participation in the ESPP would own or hold, 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the ESPP.

We may make one or more offerings each year to our employees to purchase shares under the ESPP. The first offering period under the ESPP will begin and end on the dates determined by the administrator of the ESPP. Each eligible employee may elect to participate in any offering by submitting an enrollment form by such deadline as is established by the administrator of the ESPP.

Each employee who is a participant in the ESPP may purchase shares of our common stock by authorizing payroll deductions of up to _____ % of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the shares of common stock on the first business day or the last business day of the offering period, whichever is lower, provided that no more than a number of shares of common stock determined by dividing \$25,000 by the fair market value of our common stock on the offering date of such offering (or such other lesser maximum number of shares as may be established by the administrator) may be purchased by any one employee during any offering period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of our common stock, valued at the start of the offering period, under the ESPP for each calendar year during which any option granted to the employee is outstanding at any time.

In the case of and subject to the consummation of a “sale event,” as defined in the ESPP, the administrator of the ESPP, in its discretion, and on such terms and conditions as it deems appropriate, is authorized to take any one or more of the following actions under the ESPP or with respect to any right under the ESPP or to facilitate such transactions or events: (a) provide for either (i) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (ii) the replacement of such outstanding option with other options or property selected by the administrator of the ESPP in its sole discretion; (b) provide that the outstanding options under the ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (c) make adjustments in the number and type of shares of common stock (or other securities or property) subject to outstanding options under the ESPP and/or in terms and conditions of outstanding options and options that may be granted in the future; (d) provide that the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering period will end; and (e) provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee’s rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

On _____, 2024, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or Bonus Plan. The Bonus Plan provides for cash bonus payments based upon Company and individual performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our Company, or corporate performance goals, as well as individual performance objectives. The following summary describes the material terms of the Bonus Plan. This summary is not a complete description of all provisions of the Bonus Plan and is qualified in its entirety by reference to the Bonus Plan, which will be filed as an exhibit to the registration statement to which this prospectus is a part.

Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical, commercial, or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation, and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses, collaborations or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity or investment; stockholder returns; return on sales; total stockholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of the Company's common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention and recruiting and other human resources matters; operating income and/or net annual recurring revenue; or any other performance goal selected by the compensation committee, any of which may be (A) measured in absolute terms, as compared to any incremental increase, (B) measured in terms of growth, as compared to results of a peer group, (C) measured against the market as a whole, compared to applicable market indices, and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 2.5 months after the end of the year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer shall be required to be employed by us on the bonus payment date to be eligible to receive a bonus payment under the Bonus Plan. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

DIRECTOR COMPENSATION

The following table presents the compensation awarded to, earned by, or paid to each person who served as a non-employee member of our board of directors for their services to us during the year ended December 31, 2023. Non-employee directors affiliated with TPG Life Sciences Innovations, Red Tree Venture Capital, RA Capital Management, F-Prime Capital, and Biocon, Ltd., including Drs. Ng, Lukatch, Simson, and Patel, and Ms. Mazumdar-Shaw, respectively, did not receive cash or equity compensation from us for their service as directors during 2023. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2023. During the year ended December 31, 2023, Drs. Mazumdar and Cohlhepp served as members of our board of directors and received no additional compensation for their services as members of our board of directors. The compensation for the year ended December 31, 2023 received by Drs. Mazumdar and Cohlhepp, as employees of the Company, is presented in the “2023 Summary Compensation Table” above. Dr. Cohlhepp resigned from our board of directors on March 2, 2023.

2023 Director Compensation Table

| Name (1) | Fees Earned or Paid in Cash(\$)⁽¹⁾ | Option Awards (\$)⁽²⁾ | All Other Compensation (\$)⁽³⁾ | Total (\$) |
|---|--|---|--|-------------------|
| Kate Haviland, M.B.A. ⁽⁴⁾⁽⁵⁾ | 10,000 | 165,904 | — | 175,904 |
| F. Stephen Hodi, M.D. ⁽⁴⁾⁽⁶⁾ | — | — | 5,000 | 5,000 |
| Vijay Kuchroo, D.V.M., Ph.D. ⁽⁴⁾ | 30,000 | 120,657 | — | 150,657 |
| Nils Lonberg, Ph.D. ⁽⁴⁾ | 30,000 | 120,657 | — | 150,657 |
| Heath Lukatch, Ph.D. ⁽⁴⁾⁽⁷⁾ | — | — | — | — |
| Kiran Mazumdar-Shaw ⁽⁴⁾ | — | — | — | — |
| Carolyn Ng, Ph.D. ⁽⁴⁾⁽⁸⁾ | — | — | — | — |
| Ketan Patel, M.D., M.B.A. ⁽⁴⁾⁽⁹⁾ | — | — | — | — |
| Krishna Polu, M.D. ⁽⁴⁾⁽¹⁰⁾ | — | — | — | — |
| Scott Robertson, M.B.A. ⁽⁴⁾⁽⁵⁾ | 10,000 | 165,904 | — | 175,904 |
| Jake Simson, Ph.D. ⁽⁴⁾⁽⁹⁾ | — | — | — | — |

- (1) The amounts reported represent the cash fees each director received for their services to our board of directors during the year ended December 31, 2023.
- (2) The amounts reported represent the aggregate grant date fair value of stock options awarded to our directors during the fiscal year ended December 31, 2023, calculated in accordance with FASB ASC Topic 718, disregarding estimated forfeitures related to service-based vesting. For a description of the assumptions used in determining these values, see Note 11 of our consolidated financial statements included elsewhere in this prospectus. The amount reported in this column reflects the accounting cost for the option and does not correspond to the actual economic value that may be received by our directors upon the exercise of the option or any sale of the underlying shares.
- (3) The amount reported represents cash fees paid to Dr. Hodi for services as Chairman of the Company’s Scientific Advisory Board in 2023. Pursuant to the terms of the Scientific Advisory Board Letter in effect with Dr. Hodi in 2023, Dr. Hodi was entitled to compensation of \$110 per hour for services as Chair of the Scientific Advisory Board but not to exceed \$1,667 per month.
- (4) As of December 31, 2023, Drs. Ng, Lukatch, Simson, Polu, and Patel did not hold any outstanding equity awards, and Ms. Haviland and Mr. Robertson did not hold any restricted stock. As of December 31, 2023, Drs. Hod Kuchroo, and Lonberg, Messes. Haviland and Mazumdar-Shaw and Mr. Robertson held outstanding options to purchase an aggregate of 102,720; 528,400; 452,965; 550,000; 77,040; and 550,000 shares of our common stock, respectively, and Drs. Hodi, Kuchroo, and Lonberg, and Ms. Mazumdar-Shaw held 12,840; 16,050; 9,630; and 9,630 shares of restricted stock, respectively.
- (5) Ms. Haviland and Mr. Robertson were appointed to our board of directors on September 21, 2023.

- (6) Dr. Hodi resigned from our board of directors on March 2, 2023.
- (7) Dr. Lukatch was appointed to our board of directors on August 3, 2023.
- (8) Dr. Ng was appointed to our board of directors on December 6, 2023.
- (9) Drs. Simson and Patel were appointed to our board of directors on March 2, 2023.
- (10) Dr. Polu resigned from our board of directors on August 3, 2023.

Director Engagement Letters

We have entered into director engagement letters with Drs. Kuchroo, Lonberg, and Mazumdar, Messes. Mazumdar-Shaw and Haviland, and Mr. Robertson. Pursuant to these engagement letters, each such director received an initial stock option grant that vests in 16 equal quarterly installments over four years. In addition, pursuant to his or her respective director engagement letter, during 2023, Ms. Haviland and Mr. Robertson were each entitled to receive an annual cash retainer of \$40,000 and Drs. Kuchroo and Lonberg were each entitled to receive an annual cash retainer of \$30,000. The annual retainer for each of Drs. Kuchroo and Lonberg was increased to \$40,000 effective September 22, 2023. Annual cash retainers are paid quarterly in arrears. Each director is eligible to receive reimbursement for their reasonable expenses incurred in attending board of directors meetings in accordance with our generally applicable reimbursement policies.

Effective as of April 5, 2023 and for the remainder of 2023, we were party to a Scientific Advisory Board Letter with Dr. Hodi, pursuant to which he was entitled to compensation of \$110 per hour for services as Chair of the Scientific Advisory Board, not to exceed \$1,667 per month.

Non-Employee Director Compensation Policy

In connection with this offering, our board of directors intends to adopt a non-employee director compensation policy, to be effective as of the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The policy will be designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, our non-employee directors will be eligible to receive cash retainers (which will be payable quarterly in arrears and prorated for partial years of service) and equity awards as set forth below:

| | |
|---|----|
| Annual Retainer for Board Membership: | |
| Members | \$ |
| Additional retainer for non-executive chair | \$ |
| Additional Annual Retainer for Committee Membership: | |
| Audit Committee: | |
| Members (other than chair) | \$ |
| Chair | \$ |
| Compensation Committee: | |
| Members (other than chair) | \$ |
| Chair | \$ |
| Nominating and Corporate Governance Committee: | |
| Members (other than chair) | \$ |
| Chair | \$ |

In addition, the non-employee director compensation policy will provide that, upon initial election or appointment to our board of directors, each non-employee director will be granted an equity award with a value of \$ _____, or Initial Grant. The Initial Grant will vest _____, subject to continued service through the applicable vesting date. Furthermore, on the date of each annual meeting of stockholders following the completion of this offering, each non-employee director who continues as a non-employee director following

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such meeting will be granted an annual equity award with a value of \$ _____, or Annual Grant. The Annual Grant will vest _____, subject to continued service through the applicable vesting date. The Initial Grant and the Annual Grant are subject to full accelerated vesting upon the sale of the Company.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed \$ _____ in the first calendar year such individual becomes a non-employee director and \$ _____ in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2021, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, the lesser of \$120,000 or one percent of the average of the Company’s total assets for the last two completed fiscal years; and
- in which any of our executive officers, directors or holder of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under the sections titled “Executive Compensation” and “Director Compensation.”

Private Placement of Securities

Simple Agreements for Future Equity

In March 2022, we entered into several simple agreements for future equity, or the SAFEs, pursuant to which we received approximately \$5.4 million in exchange for our agreement to issue certain investors shares of our preferred stock upon the occurrence of subsequent financings of our preferred stock. The following table summarizes purchases of SAFEs by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Total Purchase Price |
|---------------------------------------|--------------------------------------|----------------------|
| Glentech International ⁽¹⁾ | Kiran Mazumdar-Shaw | \$ 2,000,000.00 |
| Carica Investments ⁽²⁾ | Kiran Mazumdar-Shaw | \$ 2,000,000.00 |
| Eric Mazumdar ⁽³⁾ | Claire Mazumdar, Ph.D. | \$ 150,000.00 |

- (1) Such entity is a private company limited by shares of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing member.
- (2) Such entity is a partnership firm of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing partner.
- (3) Such investor is the brother of Dr. Mazumdar, our Chief Executive Officer and a member of our board of directors.

Series Seed Extension Preferred Stock Financings

Initial Closing

In April 2022, in connection with the initial closing of our Series Seed Extension preferred stock financing, we sold an aggregate of 25,940,144 shares of our Series Seed preferred stock at a purchase price of \$1.00 per share for an aggregate purchase price of approximately \$25.9 million (inclusive of approximately \$10.0 million in outstanding principal and accrued interest of the Biocon Loan (as defined below) and \$5.4 million of the SAFEs, which were converted into shares of Series Seed preferred stock). Each share of our Series Seed preferred stock will automatically convert into share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series Seed preferred stock by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Shares of Series Seed Preferred Stock | Total Purchase Price |
|--|--------------------------------------|---------------------------------------|--------------------------------|
| Biocon Pharma Inc. ⁽¹⁾ | Kiran Mazumdar-Shaw | 9,990,144 | \$ 9,990,144.00 ⁽⁶⁾ |
| Invus Public Equities, L.P. ⁽²⁾ | — | 5,000,000 | \$ 5,000,000.00 |
| Glentech International ⁽³⁾ | Kiran Mazumdar-Shaw | 2,000,000 | \$ 2,000,000.00 ⁽⁶⁾ |
| Carica Investments ⁽⁴⁾ | Kiran Mazumdar-Shaw | 2,000,000 | \$ 2,000,000.00 ⁽⁶⁾ |
| Eric Mazumdar ⁽⁵⁾ | Claire Mazumdar, Ph.D. | 150,000 | \$ 150,000.00 ⁽⁶⁾ |

- (1) Such entity is affiliated with Biocon Limited, which holds five percent or more of our capital stock. Ms. Mazumdar-Shaw is Executive Chairperson at Biocon Limited and a member of our board of directors.
- (2) Such entity is affiliated with Invus Public Equities, L.P., or Invus, which holds five percent or more of our capital stock.
- (3) Such entity is a private company limited by shares of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing member.
- (4) Such entity is a partnership firm of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing partner.
- (5) Such investor is the brother of Dr. Mazumdar, our Chief Executive Officer and a member of our board of directors.
- (6) No cash consideration. Balances in the amounts listed above under convertible agreements or SAFEs with the Company were exchanged for Series Seed preferred stock.

Second Closing

In July 2022, in connection with the second closing of our Series Seed Extension preferred stock financing, we sold an aggregate of 5,600,000 shares of our Series Seed preferred stock at a purchase price of \$1.00 per share for an aggregate purchase price of \$5.6 million. Each share of our Series Seed preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series Seed preferred stock by related persons:

| <u>Participant</u> | <u>Affiliated Director(s) or Officer(s)</u> | <u>Shares of Series Seed Preferred Stock</u> | <u>Total Purchase Price</u> |
|---------------------------------------|---|--|-----------------------------|
| Glentech International ⁽¹⁾ | Kiran Mazumdar-Shaw | 1,000,000 | \$ 1,000,000.00 |
| Carica Investments ⁽²⁾ | Kiran Mazumdar-Shaw | 2,000,000 | \$ 2,000,000.00 |

- (1) Such entity is a private company limited by shares of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing member.
- (2) Such entity is a partnership firm of which Ms. Mazumdar-Shaw, a member of our board of directors, is the managing partner.

Third Closing and Fourth Closings

In September 2022, in connection with the third and fourth closings of our Series Seed Extension preferred stock financing, we sold an aggregate of 10,250,000 shares of our Series Seed preferred stock at a purchase price of \$1.00 per share for an aggregate purchase price of \$10.2 million. Each share of our Series Seed preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series Seed preferred stock by related persons:

| <u>Participant</u> | <u>Affiliated Director(s) or Officer(s)</u> | <u>Shares of Series Seed Preferred Stock</u> | <u>Total Purchase Price</u> |
|--|---|--|-----------------------------|
| Red Tree Venture Fund, L.P. ⁽¹⁾ | Heath Lukatch, PhD | 7,500,000 | \$ 7,500,000.00 |
| Invus Public Equities, L.P. ⁽²⁾ | — | 2,500,000 | \$ 2,500,000.00 |

- (1) Such entity is affiliated with Red Tree, which holds five percent or more of our capital stock. Dr. Lukatch is a partner at Red Tree and a member of our board of directors.
- (2) Such entity is affiliated with Invus, which holds five percent or more of our capital stock.

Series B Preferred Stock Financing

Initial Closing and Additional Closing

In March 2023, in connection with the initial and additional closings of our Series B preferred stock financing, we sold an aggregate of 37,073,162 shares of our Series B preferred stock at a purchase price of \$1.025 per share for an aggregate purchase price of approximately \$38.0 million. Each share of our Series B preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series B preferred stock by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Shares of Series B Preferred Stock | Total Purchase Price |
|---|---|---|-----------------------------|
| RA Capital Healthcare Fund, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 6,463,442 | \$ 6,625,028.05 |
| RA Capital Nexus Fund III, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 4,308,961 | \$ 4,416,685.03 |
| Red Tree Venture Fund, L.P. ⁽²⁾ | Heath Lukatch, Ph.D. | 5,994,183 | \$ 6,144,037.58 |
| Omega Fund VII, L.P. ⁽³⁾ | — | 4,795,347 | \$ 4,915,230.68 |
| Invus Public Equities, L.P. ⁽⁴⁾ | — | 2,740,198 | \$ 2,808,702.95 |

- (1) Such entity is affiliated with RA Capital Management, L.P., or collectively with its affiliates RA Capital, which holds five percent or more of our capital stock. Dr. Simson is a partner at RA Capital and a member of our board of directors.
- (2) Such entity is affiliated with Red Tree Venture Fund, L.P., or Red Tree, which holds five percent or more of our capital stock. Dr. Lukatch is the managing partner at Red Tree and a member of our board of directors.
- (3) Such entity is affiliated with Omega Fund, which holds five percent or more of our capital stock.
- (4) Such entity is affiliated with Invus, which holds five percent or more of our capital stock.

Milestone Tranche 1 Closing

In September 2023, in connection with the milestone tranche 1 closing of our Series B preferred stock financing, we sold an aggregate of 39,024,386 shares of our Series B preferred stock at a purchase price of \$1.025 per share for an aggregate purchase price of approximately \$40.0 million. Each share of our Series B preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series B preferred stock by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Shares of Series B Preferred Stock | Total Purchase Price |
|---|---|---|-----------------------------|
| RA Capital Healthcare Fund, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 6,803,624 | \$ 6,973,714.60 |
| RA Capital Nexus Fund III, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 4,535,749 | \$ 4,649,142.73 |
| Red Tree Venture Fund, L.P. ⁽²⁾ | Heath Lukatch, Ph.D. | 6,309,667 | \$ 6,467,408.68 |
| Omega Fund VII, L.P. ⁽³⁾ | — | 5,047,733 | \$ 5,173,926.33 |
| Invus Public Equities, L.P. ⁽⁴⁾ | — | 2,884,419 | \$ 2,956,529.48 |

- (1) Such entity is affiliated with RA Capital, which holds five percent or more of our capital stock. Dr. Simson is a partner at RA Capital and a member of our board of directors.
- (2) Such entity is affiliated with Red Tree, which holds five percent or more of our capital stock. Dr. Lukatch is the managing partner at Red Tree and a member of our board of directors.
- (3) Such entity is affiliated with Omega Fund, which holds five percent or more of our capital stock.
- (4) Such entity is affiliated with Invus, which holds five percent or more of our capital stock.

Milestone Tranche 2 Closing

In November 2023, in connection with the milestone tranche 2 closing of our Series B preferred stock financing, we sold an aggregate of 29,497,553 shares of our Series B preferred stock at a purchase price of \$1.025 per share for an aggregate purchase price of approximately \$30.2 million. Each share of our Series B preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series B preferred stock by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Shares of Series B Preferred Stock | Total Purchase Price |
|---|---|---|-----------------------------|
| RA Capital Healthcare Fund, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 5,142,689 | \$ 5,271,256.23 |
| RA Capital Nexus Fund III, L.P. ⁽¹⁾ | Jake Simson, Ph.D. | 3,428,459 | \$ 3,514,170.48 |
| Red Tree Venture Fund, L.P. ⁽²⁾ | Heath Lukatch, Ph.D. | 4,769,319 | \$ 4,888,551.98 |
| Omega Fund VII, L.P. ⁽³⁾ | — | 3,815,455 | \$ 3,910,841.38 |
| Invus Public Equities, L.P. ⁽⁴⁾ | — | 2,180,260 | \$ 2,234,766.50 |

- (1) Such entity is affiliated with RA Capital, which holds five percent or more of our capital stock. Dr. Simson is a partner at RA Capital and a member of our board of directors.
- (2) Such entity is affiliated with Red Tree, which holds five percent or more of our capital stock. Dr. Lukatch is the managing partner at Red Tree and a member of our board of directors.
- (3) Such entity is affiliated with Omega Fund, which holds five percent or more of our capital stock.
- (4) Such entity is affiliated with Invus, which holds five percent or more of our capital stock.

Series C Preferred Stock Financing

In December 2023, we sold an aggregate of 119,599,872 shares of our Series C preferred stock at a purchase price of \$1.3796 per share for an aggregate purchase price of approximately \$165.0 million. Each share of our Series C preferred stock will automatically convert into _____ share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series C preferred stock by related persons:

| Participant | Affiliated Director(s) or Officer(s) | Shares of Series C Preferred Stock | Total Purchase Price |
|---|---|---|-----------------------------|
| TPG LSI Rise Butterfly, LP ⁽¹⁾ | Carolyn Ng, Ph.D. | 18,121,194 | \$ 24,999,999.25 |
| RA Capital Healthcare Fund, L.P. ⁽²⁾ | Jake Simson, Ph.D. | 5,835,024 | \$ 8,049,999.12 |
| RA Capital Nexus Fund III, L.P. ⁽²⁾ | Jake Simson, Ph.D. | 10,836,474 | \$ 14,949,999.54 |
| Omega Fund VII, L.P. ⁽³⁾ | — | 5,436,358 | \$ 7,499,999.50 |
| Red Tree Venture Fund, L.P. ⁽⁴⁾ | Heath Lukatch, Ph.D. | 3,624,238 | \$ 4,999,998.75 |
| Invus Public Equities, L.P. ⁽⁵⁾ | — | 3,624,238 | \$ 4,999,998.75 |

- (1) Such entity is affiliated with TPG, which holds five percent or more of our capital stock. Dr. Ng is a partner and managing director at TPG and a member of our board of directors.
- (2) Such entity is affiliated with RA Capital, which holds five percent or more of our capital stock. Dr. Simson is a partner at RA Capital and a member of our board of directors.
- (3) Such entity is affiliated with Omega Fund, which holds five percent or more of our capital stock.
- (4) Such entity is affiliated with Red Tree, which holds five percent or more of our capital stock. Dr. Lukatch is the managing partner at Red Tree and a member of our board of directors.
- (5) Such entity is affiliated with Invus, which holds five percent or more of our capital stock.

Agreements with Our Executive Officers

Ivan Hyep Promissory Note

In September 2021, we entered into a full recourse promissory note, or the Hyep Promissory Note, with Ivan Hyep, our Chief Financial Officer, pursuant to which we loaned to Mr. Hyep \$273,600, plus interest accruing at rate of 0.86% per annum (or if higher, the applicable federal rate as of the date of the Hyep Promissory Note), due by the earliest to occur of (i) December 31, 2025, (ii) the date of certain transfers by Mr. Hyep of the collateral pledged under the Hyep Promissory Note, (iii) upon the day prior to the date a change in the Company's or Mr. Hyep's status would cause the loan to be deemed prohibited under applicable law, (iv) upon the date prior to the Company's filing of a registration statement for an initial public offering or a change of control, (v) upon acceleration of the Hyep Promissory Note in accordance with its terms or (vi) the date three months following Mr. Hyep's termination of employment with the Company. As part of the Hyep Promissory Note, Mr. Hyep pledged 616,320 shares of restricted Common Stock as collateral under the terms of a security agreement. Mr. Hyep has repaid principal and interest in the following amounts on the following dates: \$70,758 in September 2022 and \$69,282 in July 2023.

Agreements with Our Stockholders

Entities affiliated with Biocon

Entities affiliated with Biocon Limited, or collectively Biocon, is a holder of greater than 5% of our securities and Ms. Mazumdar-Shaw is the Executive Chairperson of Biocon and a member of our board of directors. Below is a summary of the transactions between Biocon and us since January 1, 2021.

Syngene Master Manufacturing Services Agreement and Syngene Master Contract Services Agreement

In April 2020, we entered into an amended and restated master manufacturing services agreement, and as amended in May 2022, August 2022 and July 2023, or the Syngene Manufacturing Services Agreement, with Syngene International Limited, or Syngene, an affiliate of Biocon. Under the Syngene Manufacturing Services Agreement, Syngene provides contract development and manufacturing for drug products pursuant to statements of work. In July 2020, we entered into a master contract services agreement, or the Syngene Contract Services Agreement, with Syngene. Under the Syngene Contract Services Agreement, Syngene provides contract research and project managements services for drug products pursuant to statements of work. We have made payments to Syngene under the Syngene Manufacturing Services Agreement and Syngene Contract Services Agreement together totaling \$429,437 in 2021, \$6,205,432 in 2022 and \$7,738,383 in 2023.

Biocon Loan Agreement

In August 2021, we entered into a Loan Agreement, with Biocon Pharma Inc., or Biocon Pharma, an affiliate of Biocon, pursuant to which we borrowed \$4.5 million, with an interest rate of 4.0% per annum. In October 2021, we amended such Loan Agreement (as amended, the Biocon Loan) pursuant to which we borrowed an additional \$4.5 million, for an aggregate amount of \$9.0 million. In April 2022, we entered into a Letter of Intent with Biocon Pharma to convert the outstanding principal and accrued interest into shares of preferred stock upon the occurrence of the subsequent Series Seed Extension preferred stock financing at a price of \$1.00 per share.

Biofusion Therapeutics Limited Services Agreement

In July 2021, the Company entered into a master services agreement with Biofusion Therapeutics Limited, or Biofusion, a wholly owned subsidiary of Biocon, or the Biofusion Services Agreement, pursuant to which Biofusion provided certain research and development services to the Company. Biofusion was acquired by Syngene on August 2, 2022, and, in connection with such acquisition, the Biofusion Services Agreement was terminated in August 2022. Upon the termination of the Biofusion Services Agreement, the Company, Biocon

and Syngene determined the Company incurred \$4.1 million for the fiscal year ended December 31, 2022 and \$3.6 million for the fiscal year ended December 31, 2021 in connection with services provided under the Biofusion Services Agreement. All of such amounts were classified as accrued expenses of the Company and repaid in full in March 2023.

Biocon Biologics Limited Agreements

In July 2019, the Company entered into a manufacturing agreement, or the BBL manufacturing agreement, with a wholly-owned subsidiary of Biocon, Biocon Biologics Limited, or BBL, formerly Biocon Biologics India Limited, an affiliate of one of our greater than 5% stockholders. The BBL manufacturing agreement is valid for five years unless earlier terminated by one of the parties. Additionally, the Company entered into a material transfer agreement in August 2023, a quality agreement and a service agreement in October 2023 and a manufacturing agreement in December 2023, or, together with the BBL manufacturing agreement, the BBL Agreements, with BBL. Pursuant to the terms of the BBL Agreements, BBL manufactures and supplies specified quantities of products to the Company to be utilized in research and development and manufacturing pursuant to purchase orders executed from time to time between the parties. For the years ended December 31, 2023 and 2022, the Company incurred \$1.2 million and \$0 in research and development expenses, respectively, under the BBL Agreements. As of December 31, 2023 and 2022, the Company owed \$0 and \$0.2 million, respectively, which were classified in accounts payable-related party. The Company believes that all transactions with BBL have been entered into in the ordinary course of business.

Agreements with other stockholders

In connection with our preferred stock financings, we entered into an investors' rights agreement, voting agreement and right of first refusal agreement, in each case, with the purchasers of our preferred stock and certain holders of our common stock.

Our second amended and restated investors' rights agreement, or the Investors' Rights Agreement, provides certain holders of our preferred stock with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to certain exceptions, including shares sold in this offering. Such participation right will terminate upon the closing of this offering. The Investors' Rights Agreement further provides certain holders of our capital stock with the right to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise filing. See the section titled "*Description of Capital Stock—Registration Rights*" appearing elsewhere in this prospectus, for additional information regarding such registration rights.

Our second amended and restated voting agreement, or the Voting Agreement, provides drag-along rights in respect of sales by certain holders of our capital stock. The Voting Agreement also contains provisions with respect to the elections of our board of directors and its composition. The rights under the Voting Agreement will terminate upon the closing of this offering.

Our second amended and restated right of first refusal and co-sale agreement, or the Right of First Refusal and Co-Sale Agreement, provides for rights of first refusal and co-sale rights in respect of sales by certain holders of our capital stock. The rights under the Right of First Refusal and Co-Sale Agreement will terminate upon the closing of this offering.

Indemnification agreements

In connection with this offering, we intend to enter into new agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services

undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for approval of related party transactions

Our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction were disclosed to our board of directors prior to their consideration of such transaction. A majority of the directors who are not interested in the transaction must approve the transaction in order for the transaction to be approved by our board of directors. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we will adopt a written related party transactions policy that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus is part is declared effective by the SEC.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of May 31, 2024, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our capital stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 316,689,742 shares of common stock deemed to be outstanding as of May 31, 2024, assuming the conversion of all outstanding shares of our redeemable convertible preferred stock immediately prior to the closing of this offering, and assuming an initial public offering price of \$ _____ per share, which is the midpoint of the offering range set forth on the cover page of this prospectus, and the percentage of beneficial ownership at this offering in the table below is based on _____ shares of common stock assumed to be outstanding after the closing of the offering. The information in the table below assumes no exercise of the underwriters' option to purchase additional shares.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Bicara Therapeutics Inc., 116 Huntington Avenue, Suite 703, Boston, MA 02116.

| Name and Address of Beneficial Owner | Shares Beneficially Owned Prior to Offering | | Shares Beneficially Owned After Offering | |
|---|---|------------|--|------------|
| | Number | Percentage | Number | Percentage |
| Greater-than-5% holders: | | | | |
| Entities affiliated with Biocon ⁽¹⁾ | 51,060,144 | 16.1% | | |
| Entities affiliated with RA Capital Management, L.P. ⁽²⁾ | 47,354,422 | 15.0% | | |
| Red Tree Venture Fund, L.P. ⁽³⁾ | 28,197,407 | 8.9% | | |
| Omega Fund VII, L.P. ⁽⁴⁾ | 19,094,893 | 6.0% | | |
| Invus Public Equities, L.P. ⁽⁵⁾ | 18,929,115 | 6.0% | | |
| TPG LSI Rise Butterfly, LP ⁽⁶⁾ | 18,121,194 | 5.7% | | |
| Named Executive Officers and Directors: | | | | |
| Claire Mazumdar, Ph.D., M.B.A. ⁽⁷⁾ | 4,688,768 | 1.5% | | |
| Ryan Cohlhepp, Pharm.D. ⁽⁸⁾ | 2,812,885 | * | | |
| Ivan Hyep, M.B.A. ⁽⁹⁾ | 1,982,982 | * | | |
| Nils Lonberg, Ph.D. ⁽¹⁰⁾ | 277,230 | * | | |
| Carolyn Ng, Ph.D. | — | — | | |
| Vijay Kuchroo, D.V.M., Ph.D. ⁽¹¹⁾ | 412,050 | * | | |
| Kiran Mazumdar-Shaw ⁽¹²⁾ | 58,262,374 | 18.4% | | |
| Heath Lukatch, Ph.D. | — | — | | |

| | Shares Beneficially Owned Prior to Offering | | Shares Beneficially Owned After Offering | |
|--|---|--------------|--|------------|
| | Number | Percentage | Number | Percentage |
| Jake Simson, Ph.D. | — | — | | |
| Ketan Patel, M.D., M.B.A. | — | — | | |
| Kate Haviland, M.B.A. ⁽¹³⁾ | 103,125 | * | | |
| Scott Robertson, M.B.A. ⁽¹⁴⁾ | 103,125 | * | | |
| All executive officers and directors as a group (14 persons)⁽¹⁵⁾ | 69,154,110 | 21.1% | | |

* Less than one percent.

- (1) Consists of (i) 1,070,000 shares of common stock and 40,000,000 shares issuable upon the conversion of the Series Seed redeemable convertible preferred stock held by Biocon Limited, or Biocon Ltd, and (ii) 9,990,144 shares issuable upon the conversion of the Series Seed redeemable convertible preferred stock held by Biocon Pharma Inc., or Biocon Pharma. Kiran Mazumdar-Shaw, a member of our board of directors, is the managing member of Biocon Ltd and Biocon Pharma and may be deemed to have voting and dispositive power with respect to the shares held by Biocon Ltd and Biocon Pharma, and Ms. Mazumdar-Shaw may be deemed to beneficially own the shares held by Biocon Ltd. and Biocon Pharma. The address for Biocon Ltd is 20th KM, Hosur Road, Electronic City, Bangalore - 560100, and the address for Biocon Pharma is 485 State Hwy 1 South, Suite B 305, Iselin, NJ 08830.
- (2) Consists of (i) 18,409,755 shares issuable upon the conversion of the Series B convertible preferred stock and 5,835,024 shares issuable upon the conversion of the Series C redeemable convertible preferred stock held by RA Capital Healthcare Fund, L.P., or RA Healthcare, (ii) 12,273,169 shares issuable upon the conversion of the Series B redeemable convertible preferred stock and 10,836,474 shares issuable upon the conversion of the Series C redeemable convertible preferred stock held by RA Capital Nexus Fund III, L.P., or RA Nexus, RA Capital Management, L.P., or RA Capital is the investment manager for RA Healthcare and RA Nexus. The general partner of RA Capital is RA Capital Management GP, LLC, or RA Capital GP, of which Peter Kolchinsky and Rajeev Shah are the managing members. RA Capital, RA Capital GP, Peter Kolchinsky and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by RA Healthcare, RA Nexus. RA Capital, RA Capital GP, Peter Kolchinsky, and Rajeev Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of RA Capital is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.
- (3) Consists of (i) 7,500,000 shares issuable upon conversion of our Series Seed redeemable convertible preferred stock directly held by Red Tree Venture Fund, L.P., or Red Tree Fund I, (ii) 17,073,169 shares issuable upon conversion of our Series B redeemable convertible preferred stock directly held by Red Tree Fund I and (iii) 3,624,238 shares issuable upon conversion of our Series C redeemable convertible preferred stock directly held by Red Tree Fund I. Red Tree GP, L.P., or Red Tree GP I, is the general partner of Red Tree Fund I and may be deemed to have sole voting and dispositive power over the shares held by Red Tree Fund I. Red Tree GP I and Heath Lukatch, the Managing Director of Red Tree GP I who may be deemed to share voting and dispositive power over the reported securities, disclaim beneficial ownership of the reported securities held by Red Tree Fund I except to the extent of any pecuniary interest therein. The principal address for Red Tree Venture Fund, L.P. is 2055 Woodside Road, Suite 270, Redwood City, California 94061.
- (4) Consists of (i) 13,658,535 shares issuable upon conversion of our Series B redeemable convertible preferred stock directly held by Omega Fund VII, L.P., or Omega Fund, and (ii) 5,436,358 shares issuable upon conversion of our Series C redeemable convertible preferred stock directly held by Omega Fund. Omega Fund VII GP Manager, Ltd., or Omega Ltd, is the sole general partner of Omega Fund VII GP, L.P., or Omega GP, which is the sole general partner of Omega Fund; and each of Omega Ltd. and Omega GP may be deemed to own beneficially the shares held by Omega Fund. Claudio Nessi, Francesco Draetta and Otello Stampacchia are the directors of Omega Ltd. and, as a result, may be deemed to share voting and investment power over the shares held directly by Omega Fund. Each of Dr. Stampacchia, Mr. Draetta, Dr. Nessi, Omega Ltd. and Omega GP disclaim beneficial ownership of the shares held by Omega Fund except to the

extent of their pecuniary interest therein. The business address of the Omega Fund and its affiliates is 888 Boylston Street, Suite 1111, Boston, MA 02199.

- (5) Consists of (i) 7,500,000 shares issuable upon conversion of our Series Seed redeemable convertible preferred stock directly held by Invus Public Equities, L.P., or Invus PE, (ii) 7,804,877 shares issuable upon conversion of our Series B redeemable convertible preferred stock directly held by Invus PE and (iii) 3,624,238 shares issuable upon conversion of our Series C redeemable convertible preferred stock directly held by Invus PE. Invus Public Equities Advisors, LLC, or Invus PE Advisors controls Invus PE, as its general partner and accordingly, may be deemed to beneficially own the shares held by Invus PE. The Geneva branch of Artal International S.C.A., or Artal International controls Invus PE Advisors, as its managing member and accordingly, may be deemed to beneficially own the shares held by Invus PE. Artal International Management S.A., or Artal International Management, as the managing partner of Artal International, controls Artal International and accordingly, may be deemed to beneficially own the shares that Artal International may be deemed to beneficially own. Artal Group S.A., or Artal Group, as the sole stockholder of Artal International Management, controls Artal International Management and accordingly, may be deemed to beneficially own the shares that Artal International Management may be deemed to beneficially own. Westend S.A., or Westend, as the parent company of Artal Group, controls Artal Group and accordingly, may be deemed to beneficially own the shares that Artal Group may be deemed to beneficially own. Stichting Administratiekantoor Westend, or the Stichting, as majority shareholder of Westend, controls Westend and accordingly, may be deemed to beneficially own the shares that Westend may be deemed to beneficially own. Mr. Amaury Wittouck, as the sole member of the board of the Stichting, controls the Stichting and accordingly, may be deemed to beneficially own the shares that the Stichting may be deemed to beneficially own. The address for Invus PE and Invus PE Advisors is 750 Lexington Avenue, 30th Floor, New York, NY 10022. The address for Artal International, Artal International Management, Artal Group, Westend and Mr. Wittouck is Valley Park, 44, Rue de la Vallée, L-2661, Luxembourg. The address for the Stichting is Claude Debussylaan, 46, 1082 MD Amsterdam, The Netherlands.
- (6) Consists of 18,121,194 shares issuable upon the conversion of the Series C convertible and redeemable preferred stock held by TPG LSI Rise Butterfly, LP, or TPG LSI. TPG LSI SPV GP, LLC, or TPG GP, is the general partner of TPG LSI. TPG, Inc. is the ultimate controller of TPG LSI and TPG GP and indirectly makes the voting decisions with respect to shares held by TPG LSI. The address of these entities is 301 Commerce Street, Suite 3300, Fort Worth, Texas, US 76102.
- (7) Consists of (i) 1,951,680 shares of restricted common stock and (ii) 2,737,088 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (8) Consists of (i) 1,027,200 shares of restricted common stock and (ii) 1,785,685 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (9) Consists of (i) 616,320 shares of common stock subject to an underlying option with an early exercise feature and (ii) 1,366,662 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (10) Consists of 277,230 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (11) Consists of 412,050 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (12) See footnote 1 above. In addition, consists of (i) 3,000,000 shares issuable upon the conversion of the Series Seed redeemable convertible preferred stock held by Glentech International, a private company limited by shares of which Ms. Mazumdar-Shaw is the managing member, (ii) 4,000,000 shares issuable upon the conversion of the Series Seed redeemable convertible preferred stock held by Carica Investments, a partnership firm of which Ms. Mazumdar-Shaw is the managing partner, (iii) 154,080 shares of restricted common stock and (iv) 48,150 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (13) Consists of 103,125 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.
- (14) Consists of 103,125 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024.

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- (15) See notes (7) through (14) above; also includes (i) 676,769 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024 held by David Raben, M.D., the Company's Chief Medical Officer and (ii) 112,500 shares of common stock subject to underlying options exercisable within 60 days of May 31, 2024 held by Lara Meisner, the Company's Chief Legal Officer.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our fifth amended and restated certificate of incorporation, which will be effective immediately prior to the closing of this offering and amended and restated bylaws, which will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our fifth amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Immediately prior to the completion of this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.0001 per share, and _____ shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of May 31, 2024, 316,689,743 shares of our common stock were outstanding and held by 67 stockholders of record. This amount assumes the conversion of all outstanding shares of our convertible and redeemable preferred stock into common stock, which will occur immediately prior to the closing of this offering and includes unvested restricted common stock and unvested early exercise stock options as of May 31, 2024.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Immediately prior to the completion of this offering, all outstanding shares of our redeemable convertible preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to _____ shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of May 31, 2024, 42,755,946 shares of common stock were issuable upon the exercise of outstanding stock options under the 2019 Plan, at a weighted-average exercise price of \$0.5 per share; no shares of common stock were issuable upon exercise of outstanding stock options outside of our 2019 Plan; and shares of our common stock were reserved for future issuance under the 2024 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2024 Plan and any shares underlying outstanding stock awards granted under the 2021 Plan, that expire or are repurchased, forfeited, cancelled, or withheld. For additional information regarding terms of our equity incentive plans, see the section titled “*Executive Compensation—Employee Benefit and Equity Compensation Plans.*”

Registration Rights

Upon the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of redeemable convertible preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an investors’ rights agreement between us and the holders of our redeemable convertible preferred stock. The investors’ rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning six months after the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our redeemable convertible preferred stock upon closing of this offering, will be entitled to demand registration rights. Under the terms of the investors’ rights agreement, we will be required, upon the written request of at least ten percent (10%) of the holders of the registerable securities then outstanding that would result in an aggregate offering price of at least \$10,000,000, to file a registration statement on Form S-1 with respect to the registerable securities then outstanding and to use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale.

Short-form Registration Rights

Upon the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our redeemable convertible preferred stock upon closing of this offering, are also entitled to short-form registration rights. Pursuant to the investors’ rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least twenty percent (20%) in interest of these holders to sell registrable securities at an aggregate price of at least \$4,000,000, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only one registration in any twelve month period pursuant to this provision of the investor rights agreement.

Piggyback Registration Rights

Upon the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our redeemable convertible preferred stock upon closing of this offering, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the investors’ rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The demand registration rights and short-form registration rights granted under the investor rights agreement will terminate on the fourth anniversary of the completion of this offering.

Anti-takeover Effects of Our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws will include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to

our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for _____ authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our bylaws will provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or amended and restated bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability

created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our bylaws will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our bylaws will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

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- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Nasdaq Global Market Listing

Our common stock is currently not listed on any securities exchange. We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol "BCAX."

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of December 31, 2023, upon the completion of this offering, _____ shares of our common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal _____ shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of December 31, 2023; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under the section titled "*Underwriting*" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them

from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of the representatives, subject to certain exceptions. See the section titled “*Underwriting*” appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section titled “*Description of Capital Stock—Registration Rights*” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, all as in effect on the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and also does not address any U.S. federal non-income tax consequences, such as estate or gift tax consequences, or any tax consequences arising under any state, local or foreign tax laws. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- U.S. expatriates, former citizens, or long-term residents of the United States;
- partnerships or other entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes (and investors therein);
- “controlled foreign corporations”;
- “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that elect to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our common stock;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or synthetic security or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level.

Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any organization taxable as a corporation for U.S. federal income taxes that is not created or organized under the laws of the United States, any state thereof, or the District of Columbia; or
- a foreign trust or estate, the income of which is not subject to U.S. federal income tax on a net income basis.

Distributions on our Common Stock

As described under the section titled “*Dividend Policy*,” we do not currently anticipate declaring or paying, for the foreseeable future, any distributions on our capital stock. However, if we were to distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of the dividends and must be updated periodically. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade or business (and are attributable to such holder’s permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder generally will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. Holder’s conduct of a trade or business within the United States to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as

if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected dividends, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled "*Gain on sale or other taxable disposition of our common stock*" below.

Gain on Disposition of our Common Stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other taxable disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not "regularly traded" on an established securities market during the calendar year in which the sale or other disposition occurs.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.- source capital losses of the non-U.S. Holder (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our worldwide real property interests and our other trade or business assets. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC. Even if we are treated as a USRPHC, gain realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the non-U.S. holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition

or (b) the holder's holding period and (2) our common stock is "regularly traded" on an established securities market within the meaning of applicable U.S. Treasury regulations. There can be no assurance that our common stock qualifies as regularly traded on an established securities market for purposes of the rules described above.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of distributions on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise establishes an exemption, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally imposes a U.S. federal withholding tax of 30% on certain payments made to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent a certification that it does not have any "substantial United States owners" or provides information identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. However, proposed regulations under FATCA provide for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of from property of a type that can produce U.S. source dividends or interest. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA withholding does not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, TD Securities (USA) LLC, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares of common stock indicated below:

| <u>Name</u> | <u>Number of Shares</u> |
|--|-------------------------|
| Morgan Stanley & Co. LLC | |
| TD Securities (USA) LLC | |
| Cantor Fitzgerald & Co. | |
| Stifel, Nicolaus & Company, Incorporated | |
| Total: | |

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ _____ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to _____ additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional _____ shares of common stock.

| | <u>Per Share</u> | <u>Total</u> | |
|---|------------------|--------------------|----------------------|
| | | <u>No Exercise</u> | <u>Full Exercise</u> |
| Public offering price | \$ | \$ | \$ |
| Underwriting discounts and commissions: | \$ | \$ | \$ |
| Proceeds, before expenses, to us | \$ | \$ | \$ |

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We intend to have our common stock listed on The Nasdaq Global Market under the symbol “BCAX.”

We and all directors and officers and substantially all of the holders of all of our outstanding common stock, stock options and other securities convertible into, exercisable or exchangeable for our common stock outstanding immediately prior to the closing of this offering have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and TD Securities (USA) LLC on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus, or the restricted period:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agree that, without the prior written consent of Morgan Stanley & Co. LLC and TD Securities (USA) LLC on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to our directors, officers and securityholders with respect to:

- a) transactions relating to shares of common stock or other securities acquired (i) from the underwriters in this offering (other than any issuer-directed shares of common stock purchased in this offering by an officer or director) or (ii) in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act is required or voluntarily made during the restricted period in connection with subsequent sales of common stock or other securities acquired in this offering or such open market or other transactions (other than (1) Schedule 13 filings filed with the SEC and (2) any Form 4 or Form 5 required to be filed under the Exchange Act if the undersigned is subject to Section 16 reporting under the Exchange Act and indicating by footnote disclosure or otherwise the nature of the transaction and that such securities were acquired from the underwriters in this offering or in open market transactions after completion of this offering);
- b) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift or to a charitable organization or educational institution, (ii) to any immediate family member or any trust for the direct or indirect benefit of the party subject to the lock-up agreement or an immediate family member of such party, or if such party is a trust, to a grantor, trustee or beneficiary of the trust (including such beneficiary’s estate) or (iii) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the party subject to the lock-up agreement upon death; provided that, (i) such transfer does not involve a disposition for value, (ii) each donee or transferee signs and delivers

a lock-up agreement substantially in the form described in this prospectus and (iii) no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of common stock is required or voluntarily made during the restricted period;

- c) if the party subject to the lock-up agreement is an entity, transfers, dispositions or distributions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) to another corporation, partnership, limited liability company, investment fund trust or other business entity that is a subsidiary or an affiliate (within the meaning set forth in Rule 405 under the Securities Act of 1933, as amended, and including the subsidiaries of the party subject to the lock-up agreement) of such party, (ii) to any investment fund or other entity controlling, controlled by, managing or managed by or under common control or management with such party (including, for the avoidance of doubt, where such party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership) or (iii) to its stockholders, limited partners, general partners, members, beneficiaries or other equityholders or to the estate of any such stockholders, limited partners, general partners, members, beneficiaries or equityholders, provided that, (A) each transferee or distributee signs and delivers a lock-up agreement substantially in the form described in this prospectus, (B) no filing under the Exchange Act reporting a reduction in beneficial ownership of shares of common stock is required or voluntarily made during the restricted period and (C) such transfer does not involve a disposition for value;
- d) transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock to us (i) pursuant to any contractual arrangement in effect on the date of the lock-up agreement and described in this prospectus or (ii) in connection with the termination of the employment with or service to the Company, provided that no public disclosure or filing under Section 16(a) of the Exchange Act is required or voluntarily made during the restricted period in connection with any such transfers or dispositions (other than (1) Schedule 13 filings filed with the SEC, and (2) any Form 4 or Form 5 required to be filed under the Exchange Act if the party is subject to Section 16 reporting under the Exchange Act and indicating by footnote disclosure or otherwise the nature of the transfer or disposition);
- e) transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, common stock (including by way of “net” or “cashless” exercise solely to cover withholding tax obligations in connection with such exercise and any transfer to us for the payment of taxes as a result of such exercise) in each case pursuant to any equity incentive plan described in this prospectus and to the extent permitted by the instruments representing such options outstanding as of the date of this prospectus, provided that any remaining shares of common stock or other securities received upon such vesting, settlement or exercise remain subject to the lock-up restrictions described in this prospectus; and provided further that no public disclosure or filing is made voluntarily during the restricted period and to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period it clearly indicates that (i) the filing relates to the circumstances described in this clause (e) and (ii) no securities were sold by the party subject to the lock-up;
- f) the conversion of shares of convertible preferred stock into shares of common stock as described in this prospectus, provided that, in each case, such shares continue to be subject to the restrictions on transfer set forth in the lock-up agreement;
- g) (i) transfers of common stock or any security convertible into or exercisable or exchangeable for common stock pursuant to a bona fide third-party tender offer for shares of our capital stock made to all holders of our securities, merger, consolidation or other similar transaction approved by our board of directors the result of which is that any person (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than the Company, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the total voting power of our voting stock and

- (ii) entry into any lock-up, voting or similar agreement pursuant to which the party subject to the lock-up may agree to transfer, sell, tender or otherwise dispose of common stock or such other securities in connection with a transaction described in (i) above; provided that in the event that such change of control transaction is not completed, the common stock (or any security convertible into or exercisable or exchangeable for common stock) owned by the party subject to the lock-up agreement remains subject to the restrictions contained in the lock-up agreement; or
- h) facilitating the establishment or modification of a trading plan on behalf of a shareholder, officer or director pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock; provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the party subject to the lock-up agreement or the Company regarding the establishment of such plan, such announcement or filing includes a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

Morgan Stanley & Co. LLC and TD Securities (USA) LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us or our affiliates, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts, or NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

European Economic Area

In relation to each Member State of the European Economic Area, each a Relevant State, no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended).

Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended), or FIEL, has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors, or QII

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “QII only private placement” or a “QII only secondary distribution” (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “small number private placement” or a “small number private secondary distribution” (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures, and units of shares and debentures of that corporation or the beneficiaries’ rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired shares of our common stock under Section 275 except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (ii) where no consideration is given for the transfer; or (iii) by operation of law.

Switzerland

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of

shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

United Kingdom

In relation to the United Kingdom, no shares have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that either (i) has been approved by the Financial Conduct Authority, or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provision in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of shares may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation:

- a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000, or FSMA

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offerings and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, and the expression “UK Prospectus Regulation” means the UK version of Regulation (EU) No 2017/1129 as amended by The Prospectus (Amendment etc.) (EU Exit) Regulations 2019, which is part of UK law by virtue of the European Union (Withdrawal) Act 2018.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters related to this offering will be passed upon for the underwriters by Ropes & Gray LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Bicara Therapeutics, Inc. as of December 31, 2023 and 2022, and for the years then ended, have been included herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.bicara.com. Upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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As of and for the Years Ended December 31, 2023 and 2022

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Bicara Therapeutics Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Bicara Therapeutics Inc. and subsidiary (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

Boston, Massachusetts
June 10, 2024

BICARA THEAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and per share data)

| | <u>As of December 31,</u> | |
|---|---------------------------|------------------|
| | <u>2023</u> | <u>2022</u> |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 230,440 | \$ 4,158 |
| Prepaid expenses and other assets | 633 | 826 |
| Total current assets | <u>231,073</u> | <u>4,984</u> |
| Property and equipment, net | 202 | 636 |
| Right of use asset—operating lease | 613 | — |
| Other assets | 2,094 | 1,083 |
| Total assets | <u>\$ 233,982</u> | <u>\$ 6,703</u> |
| Liabilities, redeemable convertible preferred stock, and stockholders' deficit | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,142 | \$ 727 |
| Accounts payable—related party | 1,044 | 4,410 |
| Accrued expenses and other current liabilities | 8,053 | 6,110 |
| Accrued expenses and other current liabilities—related party | 3,561 | 12,649 |
| Operating lease liability—current portion | 285 | — |
| Total current liabilities | <u>15,085</u> | <u>23,896</u> |
| Operating lease liability—net of current portion | 372 | — |
| Other liabilities | 17 | 85 |
| Total liabilities | <u>15,474</u> | <u>23,981</u> |
| Commitments and Contingencies: | | |
| Series Seed redeemable convertible preferred stock, \$0.0001 par value, 81,790,144 and 90,940,144 shares authorized as of December 31, 2023 and 2022, respectively; 81,790,144 shares issued and outstanding as of December 31, 2023, and 2022, respectively (liquidation preference of \$81,790 as of December 31, 2023, and 2022, respectively) | 81,525 | 81,525 |
| Series B redeemable convertible preferred stock, \$0.0001 par value, 105,595,101 shares authorized; issued and outstanding as of December 31, 2023; no shares authorized, issued and outstanding as of December 31, 2022 (liquidation preference of \$108,235 and none as of December 31, 2023, and 2022, respectively) | 121,148 | — |
| Series C redeemable convertible preferred stock, \$0.0001 par value, 119,599,872 shares authorized; issued and outstanding as of December 31, 2023; no shares authorized, issued and outstanding as of December 31, 2022 (liquidation preference of \$165,000 and none as of December 31, 2023, and 2022, respectively) | 164,604 | — |
| Total redeemable convertible preferred stock | <u>367,277</u> | <u>81,525</u> |
| Stockholders' deficit: | | |
| Common stock, \$0.0001 par value, 365,000,000 and 106,000,000 shares authorized; 6,580,404 and 6,465,043 shares issued and 5,919,414 and 4,663,756 shares outstanding as of December 31, 2023, and 2022, respectively | 2 | 2 |
| Additional paid-in capital | 4,250 | 2,231 |
| Accumulated deficit | <u>(153,021)</u> | <u>(101,036)</u> |
| Total stockholders' deficit | <u>(148,769)</u> | <u>(98,803)</u> |
| Total liabilities, redeemable convertible preferred stock, and stockholders' deficit | <u>\$ 233,982</u> | <u>\$ 6,703</u> |

See accompanying notes to consolidated financial statements

BICARA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except shares and per share data)

| | <u>Year ended December 31,</u> | |
|---|--------------------------------|--------------------|
| | <u>2023</u> | <u>2022</u> |
| Operating expenses | | |
| Research and development—related party | \$ 9,244 | \$ 12,936 |
| Research and development | 21,373 | 18,376 |
| General and administrative | 9,272 | 6,344 |
| Total operating expenses | <u>39,889</u> | <u>37,656</u> |
| Loss from operations | (39,889) | (37,656) |
| Other (expenses) income | | |
| Interest expense—related party | — | (112) |
| Interest income | 1,314 | 4 |
| Change in fair value of Series B preferred stock tranche rights liability | (13,405) | — |
| Other expense, net | — | (80) |
| Total other expense | <u>(12,091)</u> | <u>(188)</u> |
| Net loss before income taxes | (51,980) | (37,844) |
| Income tax expense | (5) | (1) |
| Net loss | <u>\$ (51,985)</u> | <u>\$ (37,845)</u> |
| Net Loss per share, basic and diluted | <u>\$ (9.69)</u> | <u>\$ (9.54)</u> |
| Weighted-average number common shares outstanding, basic and diluted | <u>5,362,239</u> | <u>3,966,241</u> |

See accompanying notes to consolidated financial statements

BICARA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands except shares)

| | Series Seed Redeemable Convertible Preferred Stock | | Series B Redeemable Convertible Preferred Stock | | Series C Redeemable Convertible Preferred Stock | | Common Equity | | Additional Paid in Capital | Accumulated Deficit | Total Stockholders Deficit |
|--|--|------------------|---|------------------|---|------------------|------------------|-------------|----------------------------|---------------------|----------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| December 31, 2021 | 40,000,000 | \$ 40,000 | — | \$ — | — | \$ — | 3,110,062 | \$ 1 | \$ 1,182 | \$ (63,191) | \$ (62,008) |
| Issuance of Series Seed redeemable convertible preferred stock, net of offering cost and expenses for cash and settlement of SAFEs | 31,800,000 | 31,535 | — | — | — | — | — | — | — | — | — |
| Settlement of demand notes in exchange for Series Seed redeemable convertible preferred stock | 9,990,144 | 9,990 | — | — | — | — | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | — | — | — | — | 538,687 | 1 | 239 | — | 240 |
| Vesting of restricted common stock | — | — | — | — | — | — | 1,015,007 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | — | — | 810 | — | 810 |
| Net loss | — | — | — | — | — | — | — | — | — | (37,845) | (37,845) |
| December 31, 2022 | <u>81,790,144</u> | <u>\$ 81,525</u> | <u>—</u> | <u>\$ —</u> | <u>—</u> | <u>\$ —</u> | <u>4,663,756</u> | <u>\$ 2</u> | <u>\$ 2,231</u> | <u>\$ (101,036)</u> | <u>\$ (98,803)</u> |
| Issuance of Series B redeemable convertible preferred stock, net of offering cost, expenses, and discount | — | — | 105,595,101 | 107,101 | — | — | — | — | — | — | — |
| Issuance of Series C redeemable convertible preferred stock, net of offering cost and expenses | — | — | — | — | 119,599,872 | 164,604 | — | — | — | — | — |
| Settlement of Series B preferred stock tranche rights liability, upon issuance of milestone shares | — | — | — | 14,047 | — | — | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | — | — | — | — | 269,441 | — | 120 | — | 120 |
| Vesting of restricted common stock | — | — | — | — | — | — | 986,217 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | — | — | 1,899 | — | 1,899 |
| Net Loss | — | — | — | — | — | — | — | — | — | (51,985) | (51,985) |
| December 31, 2023 | <u>81,790,144</u> | <u>\$ 81,525</u> | <u>105,595,101</u> | <u>\$121,148</u> | <u>119,599,872</u> | <u>\$164,604</u> | <u>5,919,414</u> | <u>\$ 2</u> | <u>\$ 4,250</u> | <u>\$ (153,021)</u> | <u>\$ (148,769)</u> |

See accompanying notes to consolidated financial statements

BICARA THEAPEUTICS INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(in thousands)

| | <u>Year Ended December 31,</u> | |
|--|--------------------------------|-----------------|
| | <u>2023</u> | <u>2022</u> |
| Operating activities: | | |
| Net loss | \$ (51,985) | \$ (37,845) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Change in fair value of Series B preferred stock tranche rights liability | 13,405 | — |
| Stock-based compensation | 1,899 | 810 |
| Depreciation | 19 | 10 |
| Non-cash loss on equipment impairment | 568 | — |
| Non-cash lease expense | 90 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | (914) | (922) |
| Accounts payable and accrued expenses | 3,792 | 5,082 |
| Accounts payable and accrued expenses—related party | (12,455) | 789 |
| Operating lease liabilities | (47) | — |
| Net cash used in operating activities | <u>(45,628)</u> | <u>(32,076)</u> |
| Investing activities: | | |
| Purchase of property and equipment | (586) | (192) |
| Net cash used in investing activities | <u>(586)</u> | <u>(192)</u> |
| Financing activities: | | |
| Proceeds from issuance of preferred stock, preferred stock tranche rights and SAFEs, net | 272,347 | 31,535 |
| Proceeds from exercise of options | 149 | 160 |
| Net cash provided by financing activities | <u>272,496</u> | <u>31,695</u> |
| Net increase (decrease) in cash and cash equivalents | 226,282 | (573) |
| Cash and cash equivalents at beginning of period | 4,158 | 4,731 |
| Cash and cash equivalents at end of period | <u>\$ 230,440</u> | <u>\$ 4,158</u> |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for tax | \$ — | \$ 1 |
| Non-cash investing and financing activities: | | |
| Settlement of Series B preferred stock tranche rights liability, upon issuance of milestone shares | \$ 14,047 | \$ — |
| Right-of-use asset obtain in exchange for lease liability | \$ 703 | \$ — |
| Vesting of early exercised stock options | \$ 68 | \$ 205 |
| Property and equipment additions in accrued expenses | \$ — | \$ 432 |
| Settlement of notes payable and accrued interest with related party for Series Seed redeemable convertible preferred stock | \$ — | \$ 9,990 |

See accompanying notes to consolidated financial statements

Bicara Therapeutics Inc.

Notes to Consolidated Financial Statements

As of and for the Years Ended December 31, 2023 and 2022

In thousands, except shares and per share data

1. Description of Business, Organization, and Liquidity

Bicara Therapeutics Inc. (“Bicara” or the “Company”) was incorporated in the state of Delaware in December 2018 and is a clinical-stage biopharmaceutical company based in Boston, Massachusetts. The Company is committed to bringing transformative bifunctional therapies to patients with solid tumors. Its lead program BCA101 is a bifunctional antibody that combines a clinically validated epidermal growth factor receptor directed monoclonal antibody with a domain that binds to human transforming growth factor beta.

Since inception, the Company has operated in the preclinical and clinical stages and has devoted substantially all of its time and efforts to performing research and development activities, raising capital, and recruiting management and technical staff to support these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, risks associated with the successful research, development and manufacturing of product candidates, competition from other companies, dependence on key personnel, protection of intellectual property, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure. Even if our product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company historically has funded its operations from the issuance of redeemable convertible preferred stock, common stock and through debt financing.

In 2022, the Company sold 31,800,000 shares of its Series Seed preferred stock with par value of \$0.0001 per share (the “Series Seed Preferred Stock”) and purchase price of \$1.00 per share for net proceeds of \$31.5 million after deducting expenses paid by the Company, including the settlement of \$5.4 million of simple agreements for future equity (“SAFEs”). Additionally, as part of the Series Seed extension financing, the Company issued 9,990,144 shares of Series Seed Preferred Stock to settle the outstanding principal balance and accrued interest of an unsecured loan with Biocon as of April 26, 2022, totaling \$10.0 million.

In 2023, the Company issued 105,595,101 shares of Series B preferred stock with par value \$0.0001 per share (the “Series B Preferred Stock”) and purchase price of \$1.025 per share for net proceeds of \$107.7 million after deducting expenses paid by the Company. The Company additionally issued 119,599,872 shares of Series C preferred stock with par value of \$0.0001 per share (the “Series C Preferred Stock”) and purchase price of \$1.3796 per share for net proceeds of \$164.6 million after deducting expenses paid by the Company.

The Company has incurred operating losses since inception and expects such losses and negative operating cash flows to continue for the foreseeable future. As of December 31, 2023, the Company had cash of \$230.4 million and an accumulated deficit of \$153.0 million.

During 2022, the Company previously identified conditions and events that raised substantial doubt about its ability to continue as a going concern. During 2023, the Company raised net proceeds of \$272.3 million from the issuance of redeemable convertible preferred stock. The Company expects that its cash and cash equivalents as of December 31, 2023 of \$230.4 million will be sufficient to fund the operating expenditures and capital expenditure requirements necessary to advance its research efforts and clinical trials for at least one year from the date of issuance of these consolidated financial statements.

Bicara Therapeutics Inc.
Notes to Consolidated Financial Statements
As of and for the Years Ended December 31, 2023 and 2022

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

The Company’s consolidated financial statements include the financial position, results of operations and cash flows of Bicara. The Company’s consolidated financial statements are denominated in U.S. dollars. The consolidated financial statements include the accounts of the Company and its wholly owned, controlled subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

Reverse Stock Split

In January 2022, the Company effected a 1-for-2.3364 reverse stock split of its common stock. On the effective date of the reverse stock split, (i) each 2.3364 shares of outstanding common stock were reduced to one share of common stock; (ii) the number of shares of common stock into which each outstanding option to purchase common stock is exercisable were proportionately reduced on a 2.3364-to-1 basis; and (iii) the exercise price of each outstanding option to purchase common stock were proportionately increased on a 1-to-2.3364 basis. All the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this 1-for-2.3364 reverse stock split.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates on historical experience when available and on other assumptions that management believes are reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to: the estimated costs of research and development activities, the fair value of tranche right liabilities, and the fair values of common stock and stock awards and associated stock-based compensation expense. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Redeemable Convertible Preferred Stock

The Company recorded shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company applied the guidance in *ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities*, and therefore classified the Series Seed, Series B and Series C convertible preferred stock as mezzanine equity. The convertible preferred stock was recorded outside of stockholders’ deficit because, in the event of certain deemed liquidation events considered not solely within the Company’s control, such as a merger or consolidation and sale, lease or transfer of all or substantially all of the Company’s assets, the convertible preferred stock would have become redeemable at the

Bicara Therapeutics Inc.
Notes to Consolidated Financial Statements
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option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares would have been distributed in accordance with the corresponding liquidation preferences. The Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable at any of the reporting dates.

Series B Tranche Rights

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the consolidated financial statements. We present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value are recognized in the consolidated statements of operations.

The Series B Preferred Stock issuance as described in Note 10 Redeemable Convertible Preferred Stock to these consolidated financial statements, included tranche rights ("Series B Tranche Rights") to purchasers who participated in the initial Series B Preferred Stock issuance. The Series B Tranche Rights were determined to be a "freestanding financial instrument" as defined in the ASC Master Glossary as they are legally detachable and separately exercisable. Management assessed the freestanding financial instrument under ASC 480, Distinguishing Liabilities from Equity, and determined that such rights should be accounted for as a liability at fair value given they impose an obligation on the Company to issue shares that are contingently redeemable. The Series B Tranche Rights were revalued at each reporting period until settlement, with changes in the fair value recorded in the consolidated statements of operations.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—defined as observable inputs, such as quoted prices unadjusted in active markets for identical assets or liabilities;
- Level 2—defined as inputs other than quoted prices included in Level 1 that are either directly or indirectly observable; and
- Level 3—defined as significant unobservable inputs in which little or no market data exists, therefore, requiring an entity to develop its own assumptions

The carrying amounts of the Company's financial assets (which include cash) and liabilities (which include accounts payable) approximate fair value because of the short maturity of these instruments and have been classified as Level 1. The Series B Tranche Rights are classified as Level 3 financial liabilities (Refer to Note 3 Fair value measurement to these consolidated financial statements for more details).

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Cash and Cash Equivalents

The Company's cash and cash equivalents are held in standard checking accounts and money market funds at two financial institutions. The Company considers all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. At times, the Company's cash deposits may be in excess of insured limits. Company has not experienced any losses on its deposits of cash and does not have off-balance sheet concentrations of credit risk.

Long-Lived Assets

The Company states property and equipment at cost, net of accumulated depreciation. The Company capitalizes major improvements and expenses maintenance and repairs as incurred. The Company recognizes depreciation on a straight-line basis over the estimated useful lives of the related assets, which are as follows:

| | <u>Estimated useful Life</u> |
|-------------------------|------------------------------|
| Computers and equipment | 3 years |

Upon retirement or sale of property and equipment, as applicable, the cost and related accumulated depreciation are removed from the balance sheets and the resulting gain or loss is reflected in operations. The Company recorded a \$0.6 million loss and \$0 loss for the years ended December 31, 2023 and 2022, respectively, for property that was abandoned and written off. The Company evaluates long-lived asset impairments every year under ASC 360, noting no impairments for the years ended December 31, 2023 and 2022, respectively, except as described above.

Leases

ASC 842, Leases, requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet for all leases with a term of greater than 12 months regardless of classification. Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term discounted using an appropriate incremental borrowing rate. The incremental borrowing rate is based on the estimated interest rate for borrowing over a term similar to that of the lease payments at commencement of the lease. The operating lease expense for the operating leases is recognized on a straight-line basis over the lease term. The Company has elected the practical expedient to not separate lease and non-lease components of contracts.

The Company adopted this new standard on January 1, 2022 using the required modified retrospective approach and utilizing the effective date as its date of initial application. The adoption of this standard did not have an impact on the Company's financial statements.

Upon adoption, the Company elected, to apply the 'package of practical expedients' which permits the Company (i) not to reassess whether expired existing contracts are or contain leases, (ii) not to reassess the classification of expired or existing leases, if any, and (iii) not to reassess initial direct costs for any existing leases.

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Research and Development Expense

Research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development* (“ASC 730”). Research and development expenses include costs directly attributable to the conduct of research and development programs, including compensation costs, which includes salaries and benefits, stock-based compensation expense and the cost of services provided by outside contractors.

The Company capitalizes advance payments for goods or services that will be used or rendered for future research and development activities and recognizes expense as the related goods are delivered or services are performed. The Company also records expenses and accruals for estimated costs of research and development activities, including third party contract services for clinical research and contract manufacturing. The Company bases its estimates on the best information available at the time. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows to the Company’s vendors. Billing terms and payments are reviewed by management to ensure estimates of outstanding obligations are appropriate as of period end. Tracking the progress of completion for clinical trial and contract manufacturing activities performed by third parties allows the Company to record the appropriate expense and accruals under the terms of the agreements. During the years ended December 31, 2023 and 2022, the Company incurred \$30.6 million and \$31.3 million, respectively, relating to research and development expenses. The Company recorded accrued liabilities of \$9.6 million and \$17.2 million for clinical trial and contract manufacturing expenses as of December 31, 2023 and 2022, respectively.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and related benefits, including share-based compensation expense, related to the Company’s executive, finance and other support functions. Other general and administrative expenses include professional fees for legal, auditing, tax, consulting services, investor relations, IT and office expenses, rent and insurance.

Stock-Based Compensation

The Company accounts for stock-based employee and nonemployee compensation awards in accordance with provisions of ASC 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires the recognition of stock-based compensation expense, using a fair-value based method, for costs related to all stock-based compensation awards. We use the Black-Scholes option-pricing model to determine the fair value of options. The Black-Scholes option-pricing model requires the use of judgment to develop input assumptions, some of which are highly subjective, including: (i) the fair value of our common stock on the date of grant; (ii) the expected term of the award; (iii) the expected volatility; (iv) the risk-free interest rate; and (v) expected dividends. In applying these assumptions, we consider the following factors:

Fair Value of Common Stock: The grant date fair value of stock awards granted under its 2019 Stock Option and Grant Plan are determined using the fair market value of the Company’s common stock on the date of grant, as set forth in the applicable plan document. Due to the absence of an active market for the Company’s common stock, the Company utilized methodologies in accordance with ASC 820, *Fair Value Measurement*. The

Bicara Therapeutics Inc.
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estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, recent transactions involving the Company's stock, the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of clinical developments, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Expected Term: The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The expected life is applied to the stock option grant group as a whole as we do not expect substantially different exercise or post-vesting termination behavior among our employee population.

Expected Volatility: We used an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends due to absence of an active market for the Company's common stock.

Risk-Free Interest Rate: We based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend: We have not paid and do not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

For awards that vest based solely on achievement of a service condition, the Company recognizes expense on a straight-line basis over the period during which the award holder provides such services. The Company recognizes forfeitures as they occur and reverses any previously recognized compensation cost associated with forfeited awards. In accordance with ASU 2018-07, the Company accounts for share-based compensation for awards granted to nonemployees in a similar fashion to the way it accounts for share-based compensation awards to employees.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the asset and liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and law that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company evaluates annually the realizability of the deferred tax assets by assessing the valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2023 and 2022, the Company recorded a full valuation allowance for the deferred tax assets based on the historical loss and the uncertainty regarding the ability to project future taxable income. In future periods if the Company is able to generate income, the Company may reduce or eliminate the valuation allowance.

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Notes to Consolidated Financial Statements
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The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At December 31, 2023 and 2022, the Company had no liability for income tax associated with uncertain tax positions. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There was no income tax interest or penalties incurred during the years ended December 31, 2023 and 2022.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in equity during a period arising from transactions and other equity and circumstances, of which we have none. Our comprehensive loss equals our net loss for all periods presented.

Net Loss Per Common Share

Net loss per common share is computed using the two-class method required due to the participating nature of the redeemable convertible preferred stock. Although the redeemable convertible preferred stock are participating securities, such securities do not participate in net losses and therefore do not impact the Company's net loss from continuing operations per share calculation as of December 31, 2023 and 2022.

Basic net loss per common share is determined by dividing the net loss applicable to common shareholders by the weighted average common shares outstanding during the period. Outstanding common stock options, unvested restricted stock awards and redeemable convertible preferred shares are excluded from the calculation of diluted net loss per share when their effect would be anti-dilutive.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be anti-dilutive:

| | As of December 31, | |
|--|--------------------|------------|
| | 2023 | 2022 |
| Options and restricted stock awards outstanding | 45,273,953 | 8,177,450 |
| Series Seed redeemable convertible preferred stock | 81,790,144 | 81,790,144 |
| Series B redeemable convertible preferred stock | 105,595,101 | — |
| Series C redeemable convertible preferred stock | 119,599,872 | — |

Amounts in the table above reflect the common stock equivalents of the noted instruments.

Segments

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources.

Accounting Pronouncements Issued and Not Adopted as of December 31, 2023

Accounting Standards Update 2023-09—*Income Taxes (Topic 740): Improvements to Income Tax Disclosures, or ASU 2023-09*. ASU 2023-09 focuses on income tax disclosures around effective tax rates and

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cash income taxes paid. The standard largely follows the proposed ASU issued earlier in 2023 with several important modifications and clarifications. ASU 2023-09 is effective for public entities for annual periods beginning after December 15, 2024 and for all other business for annual periods beginning after December 15, 2025. Early adoption is permitted, and the Company is evaluating the impact of this guidance on the consolidated financial statements and related disclosures.

The Company reviewed additional recent accounting pronouncements and concluded they are either not applicable or that the Company does not expect adoption to have a material effect on the consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets that have been measured at fair value as of December 31, 2023 (in thousands):

| <u>Description</u> | <u>Level 1</u> | <u>Level 2</u> | <u>Level 3</u> | <u>December 31, 2023</u> |
|---|------------------|----------------|----------------|--------------------------|
| Assets: | | | | |
| Money market funds included within Cash and cash equivalent | \$230,088 | \$ — | \$ — | \$ 230,088 |
| Total | <u>\$230,088</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 230,088</u> |

As of December 31, 2022, the Company had no investments in money market funds.

The Company estimated the fair value of the Series B Tranche Rights at the time of issuance and subsequently remeasured them at each reporting period and prior to settlement. The fair value of the Series B Tranche Rights was determined using a contingent forward model, which considered as inputs the estimated fair value of the Series B Preferred Stock as of each valuation date, the risk-free interest rate, probability of achievement and estimated time to tranche closing. The most significant assumptions in the contingent forward model impacting the fair value of the Series B Tranche Rights are the fair value of the Company's Series B Preferred Stock, probability of achievement, and time to the tranche closing as of each measurement date. The Company determined the fair value per share of the underlying Series B Preferred Stock by taking into consideration the most recent sales of its preferred units, results obtained from third-party valuations and additional factors the Company deems relevant.

The following table sets forth a summary of the changes in fair value of the Level 3 Series B Tranche Rights for the year ended December 31, 2023 and 2022 (in thousands):

| | <u>Tranche Rights Liability</u> |
|---|---------------------------------|
| Balance as of December 31, 2022 | \$ — |
| Fair value recognized upon the issuance of preferred stock tranche rights | 642 |
| Change in the fair value of preferred stock tranche rights | 13,405 |
| Settlement of the preferred stock tranche rights | (14,047) |
| Balance as of December 31, 2023 | <u>\$ —</u> |

Bicara Therapeutics Inc.
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The following assumptions were used in the estimation of the fair value of the Series B Tranche Rights, on closing dates of Series B financing tranches (as defined in Note 10):

| | <u>November 3, 2023</u> <u>Milestone Closing</u> | <u>September 8, 2023</u> <u>Milestone Closing</u> | <u>March 2, 2023</u> <u>Initial Closing</u> |
|----------------------------|---|--|--|
| Preferred share price | \$ 1.23 | \$ 1.23 | \$ 1.01 |
| Expected term (in years) | — | — | 0.5 |
| Risk-free rate | — | — | 5.2% |
| Probability of achievement | 100.0% | 100.0% | 95.0% |

4. Leases

On August 16, 2023, the Company entered into a 2.5 years lease for 4,617 square feet of office space in Boston, Massachusetts. The lease requires a security deposit totaling \$0.1 million, which the Company has met with cash on deposit.

The Company recorded rent expense of \$0.5 million for both years ended December 31, 2023 and 2022. Rent expense incurred prior to entering into the above lease agreement was based on a month-to-month agreement.

The minimum aggregate future lease commitments are as follows (in thousands):

| | <u>Amount</u> |
|--|---------------|
| 2024 | \$ 329 |
| 2025 | 335 |
| 2026 | 56 |
| Total minimum lease payments | 720 |
| Less: imputed interest | (63) |
| Present value of lease liability | <u>\$ 657</u> |
| Other information: | |
| Weighted-average remaining lease term (in years) | 2.17 years |
| Weighted-average discount rate | 8.32% |

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

| | <u>As of December 31,</u> | |
|--|---------------------------|-----------------|
| | <u>2023</u> | <u>2022</u> |
| Accrued research and development expenses | \$ 6,035 | \$ 4,553 |
| Accrued bonus and payroll related expenses | 1,742 | 1,176 |
| Accrued professional fees | 184 | 214 |
| Accrued other | 92 | 167 |
| Total | <u>\$ 8,053</u> | <u>\$ 6,110</u> |

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6. Accrued Expenses and Other Current Liabilities—Related Party

Accrued expenses and other current liabilities—related party consisted of the following (in thousands):

| | As of December 31, | |
|--|--------------------|------------------|
| | 2023 | 2022 |
| Accrued research—related party (Note 13) | \$3,561 | \$ 12,648 |
| Accrued interest | — | 1 |
| Total | <u>\$3,561</u> | <u>\$ 12,649</u> |

7. Notes Payable to Related Party

Biocon Limited and its affiliates (“Biocon”) with which the Company conducts business, is the Company’s largest shareholder and the Executive Chairperson at Biocon is an investor and board member and is a relative of Bicara’s Chief Executive Officer.

On August 6, 2021, the Company entered into an unsecured loan agreement with Biocon providing for \$4.5 million of debt financing which was amended on October 28, 2021, pursuant to which the Company received and additional \$4.5 million unsecured loan. Interest on the outstanding loan balance accrued at a fixed annual rate of 4.0%. The Company was obligated to pay the entire loan on demand on/or before the expiry of twelve months from the date of first disbursement, whichever was earlier along with the accrued interest as of the date of repayment. On April 26, 2022, the parties amended the unsecured loan agreement, whereby the loan was extinguished with no resulting gain or loss. As part of the new agreement, the Company issued 9,990,144 shares of its Series Seed Preferred Stock for the outstanding principal balance and accrued interest as of April 26, 2022, totaling \$10.0 million.

8. Commitments and Contingencies

Legal Matters

From time to time, the Company is involved in lawsuits, arbitrations, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters, which arise in the ordinary course of business. The Company makes provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities as of December 31, 2023, and 2022.

9. Common Stock

The Company has 365,000,000 shares of Common Stock authorized for issuance, par value \$0.0001 per share, of which 6,580,404 shares issued, net of share repurchased and cancellation, and 5,919,414 shares, net were outstanding as of December 31, 2023. The Company has reserved 54,362,703 shares of Common Stock for issuance to officers, directors, employees and consultants pursuant to the 2019 Stock Option and Grant Plan (see Note 11). Of the 5,919,414 shares outstanding, 807,928 shares relate to exercise of stock options, 4,041,286 shares relate to issuance of RSAs under the 2019 Stock Option and Grant Plan, and 1,070,000 shares of Common Stock are held by Biocon and were awarded by the Company in 2020.

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10. Redeemable Convertible Preferred Stock

On December 23, 2020, the Company issued to Biocon 40,000,000 shares of Series Seed Preferred Stock (“Seed Series”) with a par value of \$0.0001 per share and purchase price of \$1.00 per share, in exchange for net proceeds of \$40.0 million. On April 26, 2022, the Company authorized for issuance an additional 50,940,144 shares of Series Seed Preferred Stock with par value of \$0.0001 per share and price of \$1.00 per share, of which 9,990,144 shares were issued to Biocon upon settlement of the related party note payable (see Note 7). On March 2, 2023, the Company reduced the total number of its authorized Series Seed Preferred Stock to 81,790,144.

In March 2022, as part of the first close of the Company’s Series Seed extension financing, the Company entered into several SAFEs, pursuant to which the Company received approximately \$5.4 million in exchange for its agreement to issue to certain investors shares of its preferred stock upon the occurrence of the Series Seed extension financing at \$1.00 per share. On April 26, 2022, the Company issued 5,350,000 shares of Series Seed Preferred Stock with par value of \$0.0001 per share and a \$1.00 per share price to settle the \$5.4 million in SAFEs, of which 4,000,000 shares of Series Seed Preferred Stock were issued to two investors controlled by a board member, who is also a relative of the Chief Executive Officer, and 350,000 shares of Series Seed Preferred Stock held by relatives of the Chief Executive Officer.

In July 2022, as part of the second close of the Company’s Series Seed extension financing, the Company sold an additional 3,000,000 shares of Series Seed Preferred Stock to the two investors controlled by a board member, who is also a relative of the Chief Executive Officer, referred to above increasing their ownership to 7,000,000 shares of Series Seed Preferred Stock.

On March 2, 2023, the Company issued 37,073,162 shares of Series B Preferred Stock at a price of \$1.025 per share (the “Initial Series B Closing”) for net proceeds of \$37.8 million.

The Company was also obligated to sell up to 68,521,939 additional shares (the “Milestone Shares”) of Series B Preferred Stock to the same purchasers at the same purchase price as the Initial Series B Closing the Series B Tranche Rights. The sale of Milestone Shares (the “Milestone Closings”) was contingent upon the Company’s achievement of certain milestones. In addition, if elected by a purchaser, the Company was obligated to sell Milestone Shares prior to achievement of the milestones (the “Voluntary Closings”). The Series B Tranche Rights are considered a freestanding instrument classified as a liability under ASC 480. The initial fair value of the liability was determined to be \$0.6 million. Refer to Note 3 Fair Value Measurements to these consolidated financial statements for further details. Share issuances pursuant to exercise of the Series B Tranche Rights under such Milestone Closings occurred on September 8 and November 3, 2023 in the amounts of 39,024,386 and 29,497,553, respectively, for net proceeds of \$69.9 million. Upon completion of the Milestone Closings, such tranche liabilities of \$8.0 million and \$6.0 million on September 8, 2023 and November 3, 2023, respectively, were settled to redeemable convertible preferred stock on the consolidated balance sheets. The Voluntary Closings were not exercised by the purchasers in 2023, and this right has expired.

On December 6, 2023, the Company issued 119,599,872 shares of Series C Preferred Stock at a price of \$1.3796 per share in exchange for aggregate net proceeds of \$164.6 million. The Company additionally executed various side letters where certain purchasers have the right to tender all owned shares back to the Company for an aggregate purchase price of \$1.00 (the “Put Option”). The Put Option has no accounting implications as it is considered immaterial.

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The Series Seed Preferred Stock, Series B Preferred Stock and Series C Preferred Stock are collectively referred to as the “Preferred Stock”. As of December 31, 2023, the Preferred Stock had the following rights, preferences, and privileges:

Conversion Rights

The holders of the Preferred Stock have rights to convert the shares of Preferred Stock into shares of Common Stock (the “Conversion Rights”) at the applicable original issue price (“Conversion Price”) with a conversion ratio (“Conversion Ratio”) of 1:1.

All outstanding shares of the Preferred Stock shall be converted automatically into shares of Common Stock upon the occurrence of any of the following events: a) the closing of the sale of shares of Common Stock to the public at a price of at least \$1.7245 per share in a public offering resulting in at least \$50.0 of gross proceeds (a “Qualified IPO”); b) immediately prior to the closing of a SPAC Transaction (with at least \$50.0 million in gross proceeds) or a “reverse merger” with a publicly traded corporation; c) upon the approval of at least 60% of the Series C preferred stockholders.

Liquidation Preference

Series B and Series C Preferred Stock—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the shareholders of outstanding Series B Preferred Stock and Series C Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to its stockholders and in case of a Deemed Liquidation Event (defined as a merger or consolidation in which the Company is a constituent party, or the sale, lease, transfer, exclusive license or other disposition by the Company of all or substantially all the assets), the holders of the Series B and Series C Preferred Stock shall be entitled to be paid out of the consideration payable to stockholders or out of the available proceeds of the Company, before the Series Seed and common stockholders, an amount per share (the “Liquidation Amount”) equal to the greater of: (a) the applicable original issue price, plus any dividends declared but unpaid, or (b) such amount per share amount as would have been payable on the conversion of all Series B Preferred Stock and Series C Preferred Stock (as applicable) into Common Stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If the amount to be paid as Liquidation Amount is insufficient, then all Series B and Series C preferred stockholders shall share the assets available for distribution in proportion of their shareholding.

Series Seed Preferred Stock—The Series Seed preferred stockholders shall have priority over the common stockholders, with a liquidation preference equal to the greater of (a) the Series Seed original issue price, plus any dividends declared but unpaid thereon, or (b) such amount per share as would have been payable on the conversion of all shares of Series Seed Preferred Stock into Common Stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If upon any such liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, and after the payment of all preferential amounts required to be paid to the holders of the Series B Preferred Stock and Series C Preferred Stock, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series Seed Preferred Stock the full amount to which they shall be entitled, the holders of shares of Series Seed Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series Seed Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

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Redemption

The Preferred Stock is not redeemable except in the event of a Deemed Liquidation Event. As redemption by the holders is not within the control of the Company, all of the outstanding convertible preferred stock is classified as temporary equity in the balance sheets.

Dividends

Series B and Series C Preferred Stock—The holders of then outstanding shares of Series B Preferred Stock and Series C Preferred Stock shall be entitled to receive, only when, as and if declared by the Board of Directors of the Company, dividends at the rate of eight percent (8%) of the applicable original issue price for each share of Series B Preferred Stock or Series C Preferred Stock, prior and in preference to any declaration or payment of any other dividend on shares of Series Seed Preferred Stock or Common Stock (other than dividends on shares of Common Stock payable in shares of Common Stock) during the same calendar year. The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company unless the holders of the Series B Preferred Stock and Series C Preferred Stock then outstanding first receive a dividend on each outstanding share of Series B Preferred Stock or Series C Preferred Stock at the same rate and same time on an as-converted basis. No dividends have been declared or paid as of December 31, 2023.

Series Seed Preferred Stock—The Company shall not declare, pay or set aside any dividends on shares of Common Stock unless the holders of the Series Seed Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock at the same rate and same time on an as-converted basis. No dividends have been declared or paid as of December 31, 2023.

Voting Rights

The holders of the Preferred Stock have the same voting rights as the holders of the Common Stock, on an as-converted basis. As of December 31, 2023, the board of directors of the Company was comprised of ten members. The election of directors is determined as following:

- i. The holders of record of the shares of Series Seed Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Company
- ii. The holders of record of the shares of Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect three (3) directors of the Company
- iii. The holders of record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Company
- iv. The holders of record of the shares of common stock, \$0.0001 par value per share, of the Company, exclusively and as a separate class, shall be entitled to elect one (1) director of the Company
- v. The holders of record of the shares of Common Stock and the Preferred Stock, voting together as a single class on an as converted basis, shall be entitled to elect the balance of the total number of directors of the Company.

Any director elected as above may be removed without cause by, and only by, the affirmative vote of the holders of the class or series of capital stock entitled to elect such director or directors.

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Protective Provisions

At any time when shares of Preferred Stock are outstanding, the Company shall not do any of the following without the written consent or affirmative vote of at least 65% of the outstanding Preferred Stock holders, including at least one holder of Series C Preferred Stock who does not hold shares of any other class or series of Preferred Stock: 1) liquidate, dissolve or wind-up the business and affairs of the Company, or effect any merger or consolidation or any other Deemed Liquidation Event; 2) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Company in a manner that adversely affects the powers, preferences or rights of the Preferred Stock; 3) create, issue, or reclassify any capital stock unless the same ranks junior to the Preferred Stock with respect to its rights, preferences and privileges; 4) cause or permit any of its subsidiaries to, without approval of the Board of Directors, sell, issue, sponsor, create or distribute any digital tokens, cryptocurrency or other blockchain-based assets; 5) purchase or redeem or pay or declare any dividend or make any distribution on, any shares of capital stock of the Company other than as expressed with the Preferred Stock agreements; 6) create, issue, or authorize the issuance of any debt security or create any lien or security interest or incur other indebtedness for borrowed money; 7) create, or hold capital stock in, any subsidiary that is not wholly owned by the Company, or permit any subsidiary to create or issue any shares, or sell, transfer or otherwise dispose of any capital stock; 8) create, adopt, amend, terminate or repeal any equity (or equity-linked) compensation plan; or 9) increase or decrease the authorized number of directors constituting the Board of Directors.

Additional protective provisions for certain classes of shares include the following:

Series B Preferred Stock—For so long as at least 52,797,551 shares of Series B Preferred Stock are outstanding, the Company shall not do any of the following without the written consent or affirmative of at least 60% of the Series B holders: a) waive or otherwise forego any adjustment in the Series B Conversion Price; b) create, or authorize the creation of, or issue or obligate itself to issue shares of, or reclassify, any capital stock unless the same ranks junior to the Series B Preferred Stock with respect to its rights, preferences and privileges; or c) amend, modify, change or waive the liquidation amount applicable to the Series B Preferred Stock.

Series C Preferred Stock—For so long as at least 71,759,924 shares of Series C Preferred Stock are outstanding, the Company shall not do any of the following without the written consent or affirmative of at least 60% of the Series C holders: a) waive or otherwise forego any adjustment in the Series C Conversion Price; b) effect the conversion of the Series C Preferred Stock to Common Stock in a Qualified IPO; c) create, or authorize the creation of, or issue or obligate itself to issue shares of, or reclassify, any capital stock unless the same ranks junior to the Series C Preferred Stock with respect to its rights, preferences and privileges; or d) amend, modify, change or waive the liquidation amount applicable to the Series C Preferred Stock.

11. Stock-Based Compensation

Stock Option and Grant Plan

In 2019, the board of directors adopted, and the Company's shareholders approved, the 2019 Stock Option and Grant Plan (the "2019 Plan") under which the Company may grant equity-based incentive awards to the Company's employees, officers, directors, consultants and other key persons of the Company and its affiliates upon whose judgement, initiative, and efforts the Company largely depends for the successful conduct of its business.

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The following are awards that are authorized to be issued:

- Stock Options including Incentive Stock Options (“ISO”) or Non-Qualified Stock Options (“NQSO”);
- Restricted Stock Awards (“RSA”);
- Unrestricted Stock Awards (“URSA”); and
- Restricted Stock Units (“RSU”)

Under the 2019 Plan, as amended, the Company is authorized to issue up to 54,362,703 shares of Common Stock. Through December 31, 2023, the Company has issued RSAs, ISOs and NQSOs under the 2019 Plan. The terms of equity award agreements, including vesting requirements, were determined by the board of directors and are subject to the provisions of the 2019 Plan. Equity awards granted to employees and non-employees generally vest over a four-year period but may be granted with different vesting terms. Certain options provide for early vesting.

RSAs were issued under individual RSA agreements (the “Award Agreements”). The Award Agreements dictate vesting terms and once vested, the recipients’ restricted stock may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided in the respective Award Agreement.

Stock options granted to employees and non-employees expire no more than 10 years from the date of grant and are generally service based. A limited number of awards contain performance-based vesting criteria and for such awards that are deemed probable of vesting, the Company records expense in the period in which such determination is made through any estimated remaining vested period.

Stock-Based Compensation Expense

Stock-based compensation, measured at the grant date based on the fair value of the award, is typically recognized ratably over the requisite service period, using the straight-line method of expense attribution. When utilizing the Black-Scholes option-pricing model to determine the grant date fair value of stock options granted to employees or non-employees, we used the following weighted average assumptions:

| | Year ended December 31, | |
|----------------------------|-------------------------|---------|
| | 2023 | 2022 |
| Risk-free interest rate | 3.24% | 3.79% |
| Expected life (in years) | 6.06 | 6.06 |
| Volatility | 81.65% | 80.60% |
| Expected dividend rate | 0.00% | 0.00% |
| Fair value of common stock | \$0.41 – \$0.59 | \$ 0.48 |

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The Company recognized total stock-based compensation expense for non-employees and employees in its statements of operations as follows (in thousands):

| | Year ended December 31, | |
|----------------------------|-------------------------|---------------|
| | 2023 | 2022 |
| General and administrative | \$ 1,518 | \$ 712 |
| Research and development | 381 | 98 |
| Total | \$ 1,899 | \$ 810 |

Restricted Stock Awards

A summary of RSA award activity for non-employees and employees of the Company is as follows:

| | Number of Share | Weighted-Average Grant Date Fair Value |
|---------------------------------|--------------------|--|
| Balance as of December 31, 2022 | 1,454,607 | \$ 0.44 |
| Granted | — | — |
| Vested | (986,217) | 0.44 |
| Repurchased/forfeited | (32,100) | — |
| Balance as of December 31, 2023 | <u>436,290</u> | <u>\$ 0.44</u> |

As of December 31, 2023, total unrecognized compensation costs of \$0.2 million related to unvested stock-based compensation arrangements are expected to be recognized as expense over a weighted average period of 0.57 years.

Stock Options

A summary of options award activity for non-employees and employees of the Company is as follows:

| | Share | Weighted-Average Exercise Price | Weighted Average— Remaining Contractual Life (years) | Aggregate Intrinsic Value ⁽¹⁾ (in thousands) |
|--|-------------------|------------------------------------|---|---|
| Outstanding as of December 31, 2022 | 6,722,843 | \$ 0.47 | | |
| Granted | 38,695,705 | 0.50 | | |
| Exercised | (269,441) | 0.45 | | |
| Canceled | (311,444) | 0.46 | | |
| Outstanding as of December 31, 2023 | <u>44,837,663</u> | 0.49 | 9.50 | \$ 4,452 |
| Exercisable as of December 31, 2023 | 3,776,491 | \$ 0.44 | 8.62 | \$ 565 |
| Exercisable and expected to vest as of December 31, 2023 | <u>44,837,663</u> | | <u>9.50</u> | |

(1) The aggregate intrinsic values is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock on December 31, 2023 for the options that were in the money.

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The Company had 41,382,172 unvested stock options outstanding as of December 31, 2023. The weighted-average fair value of options granted during the year ended December 31, 2023, and 2022, was \$0.36 and \$0.30, respectively.

As of December 31, 2023, total unrecognized compensation costs of \$14.9 million related to unvested stock options are expected to be recognized as expense over a weighted average period of 3.58 years.

12. Income Taxes

The Company's provision for income taxes is not material for the years ended December 31, 2023, and 2022. The Company's deferred tax assets (liabilities) consist of the following (in thousands):

| | As of December 31, | |
|------------------------------------|--------------------|-----------|
| | 2023 | 2022 |
| Deferred tax assets | | |
| Net operating losses | \$ 21,651 | \$ 18,980 |
| Tax credit carryforwards | 1,510 | 994 |
| Intangibles | 1,633 | 1,698 |
| Accruals and reserves | — | 314 |
| R&D Section 174 Intangibles | 12,585 | 5,700 |
| Stock compensation | 307 | 70 |
| Lease liability | 174 | — |
| Other | 8 | 7 |
| Total gross deferred tax asset | 37,868 | 27,763 |
| Deferred tax liabilities—ROU asset | (163) | — |
| Valuation allowance | (37,705) | (27,763) |
| Net deferred tax asset | \$ — | \$ — |

The Company has had net operating losses ("NOLs") since inception. As of December 31, 2023, and December 31, 2022, the Company has federal net operating loss carryforwards of \$80.4 million and \$69.4 million, respectively, all of which can be carried forward indefinitely. The Company also has federal research and development tax credit carryforwards of \$1.3 million and \$ 0.8 million, respectively, available to reduce future tax liabilities, which expire at various dates beginning in 2040.

The Company has state net operating loss carryforwards of \$75.6 million and \$69.8 million as of December 31, 2023 and December 31, 2022, respectively, to reduce future state taxable income. These state NOLs carryforwards will start expiring in 2039. The Company also has state research and development tax credit carryforwards of \$0.3 million as of December 31, 2023 and 2022, available to reduce future state tax liabilities, which expire at various dates beginning in 2035.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of NOL carryforwards and research and development credit carryforwards that may be utilized annually to offset future taxable income and taxes payable. The Company has not determined whether a limitation has occurred.

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As required by ASC 740, management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which principally comprise NOL carryforwards, research and development credit carryforwards and an IPR&D license. Management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets, and as a result, a valuation allowance of \$37.7 million and \$27.8 million has been established as of December 31, 2023, and 2022, respectively. The change in the valuation allowance was \$9.9 million for the year ended December 31, 2023. The primary reason for the difference between the income tax expense recorded by the Company and the amount of income tax expense at statutory income tax rates was the change in the valuation allowance.

As of December 31, 2023 and 2022, the Company had no unrecognized tax benefits. The Company has not as yet conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations if an adjustment were required.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statements of operations. As of December 31, 2023 and 2022, the Company has no accrued interest related to uncertain tax positions. In many cases, the Company's uncertain tax positions are related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted a Section 382 and 383 study for the year ended December 31, 2023.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

| | Year Ended December 31, | |
|---|-------------------------|---------|
| | 2023 | 2022 |
| Income tax computed at federal statutory tax rate | 21.0% | 21.0% |
| State taxes, net of federal benefit | 4.1% | 6.1% |
| Change in valuation allowance | (19.1)% | (28.5)% |
| General business credit carryovers | 1.0% | 1.7% |
| Permanent differences | (5.6)% | (0.4)% |
| Other | (1.4)% | 0.1% |
| Total | 0.0% | 0.0% |

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13. Significant Agreements—Related Parties

In addition to the notes payable to Biocon that were repaid through the issuance of the Series Seed Preferred Stock (refer to Notes 7 and 10, respectively), the Company entered into a master services agreement on December 15, 2020 (the “Master Services Agreement”) with Biocon. Pursuant to the terms of the master service agreement, Biocon provided services related to research and development, clinical trials, regulatory interactions and manufacturing. The Company did not incur any expenses under the Master Services Agreement during the year ended December 31, 2023 and 2022. As of December 31, 2023, and 2022, the Company owed \$1.6 million and \$4.8 million, respectively, of which \$0 million and \$3.3 million, respectively, were classified in accounts payable-related party, and \$1.6 million for both years were classified in accrued expenses-related party on the balance sheets.

On July 23, 2019, the Company entered into a manufacturing agreement with a wholly-owned subsidiary of Biocon, Biocon Biologics Limited (“BBL”) formerly Biocon Biologics India Limited, which is valid for 5 years unless earlier terminated by one of the parties. Additionally, the Company entered into a material transfer agreement on August 17, 2023, a quality agreement on October 12, 2023, a service agreement on October 18, 2023 and a manufacturing agreement on December 15, 2023 (the “BBL Agreements”). Pursuant to the terms of the BBL Agreements, BBL manufactures and supplies specified quantities of products to Bicara to be utilized in research and development and manufacturing as per purchase orders executed from time to time between the two parties. For the years ended December 31, 2023 and 2022, the Company incurred \$1.2 million and \$0 million research and development expenses, respectively, under the BBL Agreements. As of December 31, 2023, and 2022, the Company owed \$0 million and \$0.2 million, respectively, which were classified in accounts payable-related party.

The Company additionally entered into a manufacturing agreement with a wholly-owned subsidiary of Biocon, Syngene International Limited (“Syngene”), on July 17, 2019, as amended on May 18, 2022 and on August 1, 2022, along with a master contract services agreement on July 24, 2020 (the “Syngene Agreements”). Pursuant to the terms of the Syngene Agreements, Syngene manufactures and supplies specified quantities of products to Bicara to be used in research and development as per purchase orders executed from time to time between the two parties and performs additional contract research services under the master contract services agreement. The manufacturing agreement is valid for 6 years unless earlier terminated by one of the parties, while the master contract services agreement carried a term of 2 years. For the years ended December 31, 2023, and 2022, the Company incurred \$8.4 million and \$9.0 million of research and development expenses, respectively, under the Syngene Agreements. As of December 31, 2023, and 2022, the Company owed \$2.9 million and \$4.3 million, respectively, relating to these incurred costs, of which \$1.0 million for both years were classified in accounts payable-related party and \$1.9 million and \$3.3, respectively, were classified in accrued expenses-related party on the balance sheets.

On July 1, 2021, the Company entered into a master service agreement with a wholly-owned subsidiary of Biocon, Biofusion Therapeutics Limited (“Biofusion”) (the “Biofusion Agreement”), which was terminated upon acquisition of Biofusion by Syngene on August 2, 2022. Pursuant to the terms of the Biofusion Agreement, Biofusion provided research and development services. As of December 31, 2022, the Company owed \$7.7 million in connection with services provided by Biofusion, which were classified in accrued expenses-related party on the balance sheet, of which \$4.1 million were incurred in 2022. The Company paid the full amount on March 21, 2023.

In September 2021, the Company entered into a full recourse promissory note (the “Promissory Note”) with our Chief Financial Officer (“CFO”), pursuant to which the Company loaned \$274 thousand, plus interest

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accruing at rate of 0.86% per annum (or if higher, the applicable federal rate as of the date of the Promissory Note), due by the earliest to occur of (i) December 31, 2025, (ii) the date of certain transfers of the collateral pledged under the Promissory Note, (iii) upon the day prior to the date a change in the Company's or the CFO's status would cause the loan to be deemed prohibited under applicable law, (iv) upon the date prior to the Company's filing of a registration statement for an initial public offering or a change of control, (v) upon acceleration of the Promissory Note in accordance with its terms or (vi) the date three months following the CFO's termination of employment with the Company. As part of the Promissory Note, the CFO pledged 616,320 shares of restricted Common Stock as collateral under the terms of a security agreement. The CFO has repaid principal and interest in the following amounts on the following dates: \$71 thousand in September 2022 and \$69 thousand in July 2023. There has been immaterial interest income from the Promissory Note. As of December 31, 2023, and 2022, the Company recorded \$68 thousand for both years within prepaid expenses and other assets, and \$68 thousand and \$139 thousand, respectively, within other assets on the balance sheets.

14. Significant Agreements

On October 15, 2019, the Company entered into a master clinical contract services agreement with IQVIA RDS Inc ("IQVIA"), which was amended in December 2023 to include global clinical trials Pursuant to the terms of the agreement, as amended, IQVIA will provide the Company with certain global clinical-development related services and laboratory services under separately executed statements of work ("SOWs"). In June 2021, the Company entered into an SOW with IQVIA for lab and clinical development services, to be invoiced on a monthly basis based on work performed by IQVIA. Under this SOW, Bicara agreed to provide IQVIA with an initial upfront payment of \$1.8 million, of which \$1.0 million was a refundable deposit and \$0.8 million for investigator grant payment in advance. In December 2022, Bicara entered into an authorized to proceed agreement ("ATP") with IQVIA. Under the ATP, Bicara agreed to provide IQVIA with an additional refundable deposit of \$0.9 million, which was paid in March 2023. Both the initial deposit and the ATP deposit will be held on account and reconciled against final invoices. As of December 31, 2023, the refundable deposit balance was \$1.9 million. For the years ended December 31, 2023 and 2022 the Company incurred \$11.4 million and \$6.0 million in expenses, respectively and paid \$6.8 million and \$3.7 million, respectively, to IQVIA. As of December 31, 2023 and 2022, the Company had \$1.6 million and \$0.3 million classified in accounts payable, respectively and \$4.7 million and \$2.7 million classified in accrued expenses and other current liabilities on the balance sheets.

Shares



Common Stock

PRELIMINARY PROSPECTUS

Morgan Stanley

TD Cowen

Cantor

Stifel

Until _____, 2024 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

_____, 2024

PART II**Information Not Required in Prospectus****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The Nasdaq Global Market, or Nasdaq, listing fee.

| | Amount to be Paid |
|--|------------------------------|
| SEC registration fee | \$* |
| FINRA filing fee | * |
| Nasdaq listing fee | * |
| Printing and mailing expenses | * |
| Legal fees and expenses | * |
| Accounting fees and expenses | * |
| Transfer agent and registrar fees and expenses | * |
| Miscellaneous expenses | * |
| Total | \$* |

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We will adopt provisions in our certificate of incorporation to be in effect immediately prior to the closing of this offering and bylaws to be in effect upon the effectiveness of this registration statement that limit or eliminate the personal liability of our directors and officers to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, our directors and officers will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director or officer, except for liability for:

- any breach of their duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our Directors, any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions;

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- any transaction from which the director derived an improper personal benefit; or
- for our officers, any derivative action by or in the right of the corporation.

These limitations of liability do not alter director and officer liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with our executive officers. These agreements provide that we will indemnify each of our directors, our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended (the Securities Act).

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

In December 2020, April 2022, July 2022, and September 2022, we issued and sold an aggregate of 81,790,144 shares of Series Seed redeemable convertible preferred stock at a purchase price of \$1.00 per share for an aggregate purchase price of approximately \$81.8 million.

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In March 2023, September 2023, and November 2023, we issued and sold an aggregate of 105,595,541 shares of Series B redeemable convertible preferred stock at a purchase price of \$1.025 per share for an aggregate purchase price of approximately \$108 million (including \$70.2 million of Milestone closings).

In December 2023, we issued and sold an aggregate of 119,599,872 shares of Series C redeemable convertible preferred stock at a purchase price of \$1.3796 per share for an aggregate purchase price of approximately \$165 million.

No underwriters were involved in the foregoing sales of securities. Unless otherwise stated, the sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Since May 31, 2021, we have granted stock options to purchase an aggregate of 48,596,371 shares of our common stock, with a weighted average exercise price of \$0.68 per share, to employees, directors and consultants pursuant to the 2019 Plan. Since May 31, 2021, 4,003,708 shares of common stock have been issued upon the exercise of stock options pursuant to the 2019 Plan. Since May 31, 2021, 2,309,237 stock options previously issued pursuant to the 2019 Plan have been cancelled and forfeited.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 1.1* | Form of Underwriting Agreement. |
| 3.1 | Fourth Amended and Restated Certificate of Incorporation, as currently in effect. |
| 3.2* | Form of Fifth Amended and Restated Certificate of Incorporation, to be in effect upon completion of this offering. |
| 3.3 | Bylaws of Registrant, as currently in effect. |
| 3.4* | Form of Amended and Restated Bylaws of Registrant, to be in effect upon the effectiveness of this registration statement. |
| 4.1* | Specimen Common Stock Certificate. |

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| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 4.2* | Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 6, 2023. |
| 5.1* | Opinion of Goodwin Procter LLP. |
| 10.1# | 2019 Stock Option and Grant Plan and form of award agreements thereunder. |
| 10.2*## | Bicara Therapeutics Inc. 2024 Stock Option and Incentive Plan and form of award agreements thereunder. |
| 10.3*## | Bicara Therapeutics Inc. 2024 Employee Stock Purchase Plan. |
| 10.4*## | Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers. |
| 10.5*## | Senior Executive Cash Incentive Bonus Plan. |
| 10.6*## | Form of Executive Employment Agreement. |
| 10.7*## | Non-Employee Director Compensation Policy. |
| 10.8*## | Compensation Recovery Policy. |
| 10.9† | Contract Transfer and License Agreement, by and between the Registrant and Biocon Limited, dated October 1, 2019. |
| 10.10† | Clinical Trial Collaboration and Supply Agreement, by and between the Registrant and MSD International GmbH and MSD International Business GmbH, dated May 19, 2022. |
| 10.11+ | Office Lease Agreement, dated August 16, 2023. |
| 21.1 | Subsidiaries of the Registrant. |
| 23.1* | Consent of KPMG LLP, independent registered public accounting firm. |
| 23.2* | Consent of Goodwin Procter LLP (included in Exhibit 5.1). |
| 24* | Power of Attorney (included on signature page). |

* To be filed by amendment.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

Indicates a management contract or any compensatory plan, contract or arrangement.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

(b) Financial Statements Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

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In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

- (a) The Registrant will provide to the underwriter at the closing as specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(b) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (c) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Massachusetts, on the _____ day of _____, 2024.

BICARA THERAPEUTICS INC.

By: _____
Name: Claire Mazumdar, Ph.D., M.B.A.
Title: Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints Claire Mazumdar Ph.D., M.B.A., Ryan Cohlhepp, Pharm.D. and Ivan Hyep as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following person in the capacities and on the date indicated.

| <u>Name</u> | <u>Title</u> | <u>Date</u> |
|---|--|-------------|
| _____ Claire Mazumdar, Ph.D., M.B.A. | Chief Executive Officer <i>(Principal Executive Officer)</i> | , 2024 |
| _____ Ivan Hyep, M.B.A. | President and Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i> | , 2024 |
| _____ Nils Lonberg, Ph.D. | Director, Chairperson | , 2024 |
| _____ Carolyn Ng, Ph.D. | Director | , 2024 |
| _____ Vijay Kuchroo, D.V.M., Ph.D. | Director | , 2024 |

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| <u>Name</u> | <u>Title</u> | <u>Date</u> |
|---------------------------|--------------|-------------|
| Kiran Mazumdar-Shaw | Director | , 2024 |
| Heath Lukatch, Ph.D. | Director | , 2024 |
| Jake Simson, Ph.D. | Director | , 2024 |
| Ketan Patel, M.D., M.B.A. | Director | , 2024 |
| Kate Haviland, M.B.A. | Director | , 2024 |
| Scott Robertson, M.B.A. | Director | , 2024 |

**FOURTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
BICARA THERAPEUTICS INC.**

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Bicara Therapeutics Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Bicara Therapeutics Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on December 12, 2018. The corporation’s original certificate of incorporation was (i) amended and restated by that certain Second Amended and Restated Certificate of Incorporation, dated as of December 23, 2020, (ii) amended by that certain Certificate of Amendment No. 1, dated as of January 28, 2022, (iii) further amended by that certain Certificate of Amendment No. 2, dated as of January 28, 2022, (iv) further amended by that certain Certificate of Amendment No. 3, dated as of April 26, 2022, (v) further amended by that certain Certificate of Amendment No. 4, dated as of September 14, 2022 and (vi) amended and restated by that certain Third Amended and Restated Certificate of Incorporation, dated as of March 2, 2023 (collectively, the “**Third Amended and Restated Certificate of Incorporation**”).

2. That the Board of Directors of the Corporation duly adopted resolutions proposing to amend and restate the Third Amended and Restated Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Third Amended and Restated Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is Bicara Therapeutics Inc. (the “**Corporation**”).

SECOND: The address of the registered office of the Corporation in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, 19801, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 365,000,000 shares of Common Stock, \$0.0001 par value per share (“**Common Stock**”) and (ii) 306,985,117 shares of Preferred Stock, \$0.0001 par value per share (“**Preferred Stock**”).

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. **General.** The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. **Voting.** The holders of the Common Stock are entitled to one (1) vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Fourth Amended and Restated Certificate of Incorporation (“**Certificate of Incorporation**”) that relates solely to the terms of one (1) or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one (1) or more other such series, to vote thereon pursuant to this Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one (1) or more series of Preferred Stock that may be required by the terms of this Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

81,790,144 shares of the authorized Preferred Stock are hereby designated “**Series Seed Preferred Stock**”, 105,595,101 shares of the authorized Preferred Stock are hereby designated “**Series B Preferred Stock**” and 119,599,872 shares of the authorized Preferred Stock are hereby designated “**Series C Preferred Stock**”, each with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to “Sections” in this Part B of this Article Fourth refer to sections of Part B of this Article Fourth.

1. Dividends.

1.1 **Series B Preferred Stock and Series C Preferred Stock Dividends.** The holders of then outstanding shares of Series B Preferred Stock and Series C Preferred Stock shall be entitled to receive, on a *pari passu* basis, only when, as and if declared by the Board of Directors of the Corporation (the “**Board of Directors**”), out of any funds and assets legally available therefor, dividends at the rate of eight percent (8%) of the Applicable Original Issue

Price (as defined below) for each share of Series B Preferred Stock or Series C Preferred Stock (as applicable), prior and in preference to any declaration or payment of any other dividend on shares of Series Seed Preferred Stock or Common Stock (other than dividends on shares of Common Stock payable in shares of Common Stock) during the same calendar year. The right to receive dividends on shares of Series B Preferred Stock and Series C Preferred Stock pursuant to the preceding sentence of this Section 1.1 shall not be cumulative, and no right to dividends shall accrue to holders of Series B Preferred Stock or Series C Preferred Stock by reason of the fact that dividends on said shares are not declared. The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Certificate of Incorporation) the holders of the Series B Preferred Stock and Series C Preferred Stock then outstanding shall first receive, or simultaneously receive, in addition to the dividends payable pursuant to the first sentence of this Section 1.1, a dividend on each outstanding share of Series B Preferred Stock and Series C Preferred Stock (as applicable) in an amount at least equal to (i) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Series B Preferred Stock or Series C Preferred Stock (as applicable) as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (B) the number of shares of Common Stock issuable upon conversion of a share of Series B Preferred Stock or Series C Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Series B Preferred Stock or Series C Preferred Stock (as applicable) determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the Applicable Original Issue Price; provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Series B Preferred Stock and Series C Preferred Stock pursuant to this Section 1.1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Series B Preferred Stock or Series C Preferred Stock dividend (as applicable).

1.2 Series Seed Preferred Stock Dividends. The holders of the Series Seed Preferred Stock then outstanding shall be entitled to receive, only when, as and if declared by the Board of Directors, dividends, out of any funds and assets legally available therefor, prior and in preference to any declaration or payment of any other dividend (other than (i) dividends on shares of Series B Preferred Stock and Series C Preferred Stock pursuant to Section 1.1 above and (ii) dividends on shares of Common Stock payable in shares of Common Stock) in the amounts designated by the Board of Directors and payable only when, as and if, declared by the Board of Directors. The right to receive dividends on shares of Series Seed Preferred Stock pursuant to the preceding sentence of this Section 1.2 shall not be cumulative, and no right to dividends shall accrue to holders of Series Seed Preferred Stock by reason of the fact that dividends on said shares are not declared. The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than

dividends on shares of Common Stock payable in shares of Common Stock and dividends to the holders of the Series B Preferred Stock and Series C Preferred Stock) unless (in addition to the obtaining of any consents required elsewhere in this Certificate of Incorporation) the holders of Series Seed Preferred Stock then outstanding shall receive, after the payment of any dividend required to be paid on any outstanding share of Series B Preferred Stock and Series C Preferred Stock, (i) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Series Seed Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (B) the number of shares of Common Stock issuable upon conversion of a share of Series Seed Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Series Seed Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the Series Seed Original Issue Price (as defined below); provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Series Seed Preferred Stock pursuant to this Section 1.2 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Series Seed Preferred Stock dividend.

1.3 Original Issue Price. The “**Series Seed Original Issue Price**” shall mean, with respect to the Series Seed Preferred Stock, \$1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series Seed Preferred Stock. The “**Series B Original Issue Price**” shall mean, with respect to the Series B Preferred Stock, \$1.025 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock. The “**Series C Original Issue Price**” shall mean, with respect to the Series C Preferred Stock, \$1.3796 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock. The “**Applicable Original Issue Price**” shall mean (i) the Series Seed Original Issue Price, in the case of the Series Seed Preferred Stock, (ii) the Series B Original Issue Price, in the case of the Series B Preferred Stock and (iii) the Series C Original Issue Price, in the case of the Series C Preferred Stock.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Series B Preferred Stock and Series C Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series B Preferred Stock and Series C Preferred Stock then outstanding shall be entitled to be paid, on a *pari passu* basis, out of the assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined below), the holders of shares of Series B Preferred Stock and

Series C Preferred Stock then outstanding shall be entitled to be paid, on a *pari passu* basis, out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the Available Proceeds (as defined below), as applicable, before any payment shall be made to the holders of Common Stock and Series Seed Preferred Stock by reason of their ownership thereof, an amount per share equal to (a) in the case of Series B Preferred Stock, the greater of (i) the Series B Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series B Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event and (b) in the case of Series C Preferred Stock, the greater of (i) the Series C Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series B Preferred Stock and Series C Preferred Stock the full amount to which they shall be entitled under this Section 2.1, the holders of shares of Series B Preferred Stock and Series C Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series B Preferred Stock and Series C Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. The amount which a holder of a share of Series B Preferred Stock or a holder of a share of Series C Preferred Stock is entitled to receive under this Section 2.1 and the amount which a holder of a share of Series Seed Preferred Stock is entitled to receive under Section 2.2 below is hereinafter referred to as the “**Applicable Preferred Stock Liquidation Amount**” with respect to such share.

2.2 Preferential Payments to Holders of Series Seed Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after payment of all preferential amounts required to be paid to holders of Series B Preferred Stock and Series C Preferred Stock pursuant to Section 2.1, the holders of shares of Series Seed Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event, the holders of shares of Series Seed Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the Available Proceeds, as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series Seed Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series Seed Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, and after the payment of all preferential amounts required to be paid to the holders of the Series B Preferred Stock and Series C Preferred Stock pursuant to Section 2.1, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series Seed Preferred Stock the full amount to which they shall be entitled under this Section 2.2, the holders of shares of Series Seed Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series Seed Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.3 Payments to Holders of Common Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment in full of all Applicable Preferred Stock Liquidation Amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, the consideration not payable to the holders of shares of Preferred Stock pursuant to Section 2.1 or 2.2 or the remaining Available Proceeds, as the case may be, shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares of Common Stock held by each such holder.

2.4 Deemed Liquidation Events.

2.4.1 Definition. Each of the following events shall be considered a “**Deemed Liquidation Event**” unless the Requisite Holders (as defined below) elect otherwise by written notice sent to the Corporation at least ten (10) days prior to the effective date of any such event:

(a) a merger or consolidation in which

- (i) the Corporation is a constituent party or
- (ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) (i) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or (ii) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one (1) or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

(c) For all purposes under this Certificate of Incorporation, the “**Requisite Holders**” shall mean the holders of at least sixty-five percent (65%) of the outstanding shares of Preferred Stock (voting together as a single class on an as-converted to Common Stock basis), which must include at least one (1) holder of Series C Preferred Stock who does not hold shares of any other class or series of Preferred Stock, so long as there is such a holder of Series C Preferred Stock.

2.4.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Section 2.4.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the “**Merger Agreement**”) provides that the consideration payable to the stockholders of the Corporation in such Deemed Liquidation Event shall be allocated to the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2 and 2.3.

(b) In the event of a Deemed Liquidation Event referred to in Section 2.4.1(a)(ii) or 2.4.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice (the “**Redemption Notice**”) to each holder of Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the Requisite Holders so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the “**Available Proceeds**”), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share equal to the Applicable Preferred Stock Liquidation Amount. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall redeem a pro rata portion of each holder’s shares of Preferred Stock to the fullest extent of such Available Proceeds, in accordance with the priority of payments set forth in Sections 2.1 and 2.2 and the respective amounts which would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders in accordance with the priority of payments set forth in Sections 2.1 and 2.2. Prior to the distribution or redemption provided for in this Section 2.4.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business. With respect to any redemption required by this Section 2.4.2(b), each Redemption Notice shall state:

- (i) the number of shares and series of Preferred Stock held by the holder that the Corporation shall redeem;

- (ii) the date of redemption (the “**Redemption Date**”) and price per share of each series of the Preferred Stock to be redeemed held by such holder (the “**Redemption Price**”);
- (iii) the date upon which the holder’s right to convert such shares terminates (as determined in accordance with Section 4.1); and
- (iv) that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of the Preferred Stock to be redeemed.

If the Corporation receives, on or prior to the twentieth (20th) day after the date of delivery of the Redemption Notice to a holder of Preferred Stock, written notice from such holder that such holder elects to be excluded from the redemption provided in this Section 2.4, then the shares of Preferred Stock registered on the books of the Corporation in the name of such holder at the time of the Corporation’s receipt of such notice shall thereafter be “**Excluded Shares**.” Excluded Shares shall not be redeemed or redeemable pursuant to this Section 2.4 (and, for the avoidance of doubt, will not be subject to the provisions of Section 2.4.2(c) and (d)), whether on such Redemption Date or thereafter.

(c) On or before the Redemption Date, each holder of shares of Preferred Stock, unless such holder has exercised his, her or its right to convert such shares as provided in Section 4, shall surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the Redemption Price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

(d) If any shares of Preferred Stock are not redeemed for any reason on any Redemption Date, all such unredeemed shares shall remain outstanding and entitled to all the rights and preferences provided herein, and the Corporation shall pay interest on the Redemption Price applicable to such unredeemed shares at an aggregate per annum rate equal to twelve percent (12%) (increased by one percent (1%) each month following the Redemption Date until the Redemption Price, and any interest thereon, is paid in full), with such interest to accrue daily in arrears and be compounded annually; provided, however, that in no

event shall such interest exceed the maximum permitted rate of interest under applicable law (the “**Maximum Permitted Rate**”), provided, however, that the Corporation shall take all such actions as may be necessary, including, without limitation, making any applicable governmental filings, to cause the Maximum Permitted Rate to be the highest possible rate. In the event any provision hereof would result in the rate of interest payable hereunder being in excess of the Maximum Permitted Rate, the amount of interest required to be paid hereunder shall automatically be reduced to eliminate such excess; provided, however, that any subsequent increase in the Maximum Permitted Rate shall be retroactively effective to the applicable Redemption Date to the extent permitted by law.

(e) If the Redemption Notice shall have been duly given, and if on the Redemption Date the Redemption Price payable upon redemption of the shares of Preferred Stock to be redeemed on such Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that the certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to accrue after such Redemption Date and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of their certificate or certificates therefor.

2.4.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities to be paid or distributed to such holders pursuant to such Deemed Liquidation Event. The value of such property, rights or securities shall be determined in good faith by the Board of Directors, including the approval of at least four (4) of the Preferred Directors (as defined below) (or, if fewer, such number of Preferred Directors then serving) (the “**Requisite Preferred Directors**”).

2.4.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event pursuant to Section 2.4.1(a) (i), if any portion of the consideration payable to the stockholders of the Corporation is payable only upon satisfaction of contingencies (the “**Additional Consideration**”), the Merger Agreement shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the “**Initial Consideration**”) shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2 and 2.3 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2 and 2.3 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Section 2.4.4, consideration placed into escrow or retained as a holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Additional Consideration.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of a meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

3.2 Election of Directors. The holders of record of (i) the shares of Series Seed Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation (the “**Series Seed Preferred Director**”), (ii) the shares of Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect three (3) directors of the Corporation (the “**Series B Preferred Directors**”), (iii) the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation (the “**Series C Preferred Director**” and collectively with the Series Seed Preferred Director, and Series B Preferred Directors, the “**Preferred Directors**”) and (iv) the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation; provided, however, for administrative convenience, the initial Series C Preferred Director may also be appointed by the Board of Directors in connection with the approval of the initial issuance of the Series C Preferred Stock without a separate action by the holders of Series C Preferred Stock. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Preferred Stock or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Section 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Preferred Stock or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Section 3.2, a vacancy in any directorship filled by the holders of any class or classes or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or classes or series or by any remaining director or directors elected by the holders of such class or classes or series pursuant to this Section 3.2.

3.3 Preferred Stock Protective Provisions. At any time when shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation, recapitalization, reclassification, or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the Requisite Holders given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

3.3.1 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;

3.3.2 amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation (the “**Bylaws**”);

3.3.3 (i) create, or authorize the creation of, or issue or obligate itself to issue shares of, or reclassify, any capital stock unless the same ranks junior to each series of Preferred Stock with respect to its rights, preferences and privileges, or (ii) increase the authorized number of shares of any series of Preferred Stock or any additional class or series of capital stock of the Corporation unless the same ranks junior to each series of the Preferred Stock with respect to its rights, preferences and privileges;

3.3.4 cause or permit any of its subsidiaries to, without approval of the Board of Directors, including the approval of the Requisite Preferred Directors, sell, issue, sponsor, create or distribute any digital tokens, cryptocurrency or other blockchain-based assets (collectively, “**Tokens**”), including through a pre-sale, initial coin offering, token distribution event or crowdfunding, or through the issuance of any instrument convertible into or exchangeable for Tokens;

3.3.5 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on the Preferred Stock as expressly authorized herein, (ii) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock and (iii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof or (iv) as approved by the Board of Directors, including the approval of the Requisite Preferred Directors;

3.3.6 (i) create, adopt, amend, terminate or repeal any equity (or equity-linked) compensation plan, (ii) amend or waive any of the terms of any option or other grant pursuant to any such plan or (iii) increase the amount of Common Stock reserved under such plan;

3.3.7 create, or authorize the creation of, or issue, or authorize the issuance of any debt security or create any lien or security interest (except for purchase money liens or statutory liens of landlords, mechanics, materialmen, workmen, warehousemen and other similar persons arising or incurred in the ordinary course of business) or incur other indebtedness for borrowed money, including but not limited to obligations and contingent obligations under guarantees, or permit any subsidiary to take any such action with respect to any debt security lien, security interest or other indebtedness for borrowed money, if the aggregate indebtedness of the Corporation and its subsidiaries for borrowed money following such action would exceed \$250,000 (other than equipment leases, bank lines of credit or trade payables incurred in the ordinary course), unless such debt security has received the prior approval of the Board of Directors, including the approval of the Requisite Preferred Directors;

3.3.8 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one (1) or more other subsidiaries) by the Corporation, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary; or

3.3.9 increase or decrease the authorized number of directors constituting the Board of Directors, change the number of votes entitled to be cast by any director or directors on any matter, or adopt any provision inconsistent with Article Sixth.

3.4 **Series B Preferred Stock Protective Provisions.** For so long as at least 52,797,551 shares of Series B Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock) remain outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation, recapitalization, reclassification, or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of at least sixty percent (60%) of the outstanding shares of Series B Preferred Stock (the “**Requisite Series B Holders**”) given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

3.4.1 waive or otherwise forego any adjustment in the Series B Conversion Price (as defined below) as the result of the issuance or deemed issuance of Additional Shares of Common Stock (as defined below) in accordance with Section 4.4;

3.4.2 create, or authorize the creation of, or issue or obligate itself to issue shares of, or reclassify, any capital stock unless the same ranks junior to the Series B Preferred Stock with respect to its rights, preferences and privileges; or

3.4.3 amend, modify, change or waive the Applicable Preferred Stock Liquidation Amount applicable to the Series B Preferred Stock, including, without limitation, the waiver of a Deemed Liquidation Event.

3.5 Series C Preferred Stock Protective Provisions. For so long as at least 71,759,924 shares of Series C Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock) remain outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation, recapitalization, reclassification, or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of at least sixty percent (60%) of the outstanding shares of Series C Preferred Stock (the “**Requisite Series C Holders**”) given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

3.5.1 waive or otherwise forego any adjustment in the Series C Conversion Price (as defined below) as the result of the issuance or deemed issuance of Additional Shares of Common Stock (as defined below) in accordance with Section 4.4;

3.5.2 effect the conversion of the Series C Preferred Stock to Common Stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, that is not a Qualified IPO (as defined below);

3.5.3 create, or authorize the creation of, or issue or obligate itself to issue shares of, or reclassify, any capital stock unless the same ranks junior to the Series C Preferred Stock with respect to its rights, preferences and privileges; or

3.5.4 amend, modify, change or waive the Applicable Preferred Stock Liquidation Amount applicable to the Series C Preferred Stock, including, without limitation, the waiver of a Deemed Liquidation Event.

4. Optional Conversion. The holders of the Preferred Stock shall have conversion rights as follows (the “**Conversion Rights**”):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Applicable Original Issue Price by the Applicable Conversion Price (as defined below) in effect at the time of conversion. As of the Original Issue Date, the “**Applicable Conversion Price**” shall initially be equal to (i) in the case of the Series Seed Preferred Stock, \$1.00, (ii) in the case of the Series B Preferred Stock, \$1.025 (the “**Series B Conversion Price**”) and (iii) in the case of the Series C Preferred Stock, \$1.3796 (the “**Series C Conversion Price**”). Such Applicable Conversion Price, and the rate at which shares of the applicable series of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.1.2 Termination of Conversion Rights. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock; provided that the foregoing termination of Conversion Rights shall not affect the amount(s) otherwise paid or payable in accordance with Section 2.1 to holders of Preferred Stock pursuant to such liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event.

4.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the applicable series of Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the number of shares of Common Stock to be issued upon conversion of the applicable series of Preferred Stock shall be rounded down to the nearest whole share.

4.3 Mechanics of Conversion

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder's shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, and (ii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the applicable series of Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Applicable Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the applicable series of Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Applicable Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Applicable Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Applicable Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) “**Additional Shares of Common Stock**” shall mean all shares of Common Stock issued (or, pursuant to Section 4.4.3 below, deemed to be issued) by the Corporation after the Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, “**Exempted Securities**”):

- (i) as to any series of Preferred Stock shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on such series of Preferred Stock;
- (ii) shares of Common Stock to be issued upon the conversion of the Preferred Stock;
- (iii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Section 4.5, 4.6, 4.7 or 4.8;
- (iv) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors (including the approval of the Requisite Preferred Directors);
- (v) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;
- (vi) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors (including the approval of the Requisite Preferred Directors);
- (vii) shares of Common Stock, Options or Convertible Securities issued to suppliers or third party service providers in connection with the provision of goods or services pursuant to transactions approved by the Board of Directors (including the approval of the Requisite Preferred Directors);

(viii) shares of Common Stock, Options or Convertible Securities issued as acquisition consideration pursuant to the acquisition of another corporation by the Corporation by merger, purchase of substantially all of the assets or other reorganization or to a joint venture agreement, provided that such issuances are approved by the Board of Directors (including the approval of the Requisite Preferred Directors); or

(ix) shares of Common Stock, Options or Convertible Securities issued in connection with sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnership approved by the Board of Directors (including the approval of the Requisite Preferred Directors).

(b) “**Convertible Securities**” shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(c) “**Option**” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(d) “**Original Issue Date**” shall mean the date on which the first share of Series C Preferred Stock was issued.

4.4.2 No Adjustment of Applicable Conversion Price. No adjustment in the Applicable Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Holders agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock; provided that this waiver shall not be effective as to the Series B Preferred Stock unless the Requisite Series B Holders also agree that no such adjustment shall be made to the Series B Conversion Price; provided further that this waiver shall not be effective as to the Series C Preferred Stock unless the Requisite Series C Holders also agree that no such adjustment shall be made to the Series C Conversion Price.

4.4.3 Deemed Issue of Additional Shares of Common Stock

(a) If the Corporation at any time or from time to time after the Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Applicable Conversion Price pursuant to the terms of Section 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, such Applicable Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Applicable Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Applicable Conversion Price to an amount which exceeds the lower of (i) the Applicable Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Applicable Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Applicable Conversion Price pursuant to the terms of Section 4.4.4 (either because the consideration per share (determined pursuant to Section 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Applicable Conversion Price then in effect, or because such Option or Convertible Security was issued before the Original Issue Date), are revised after the Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Section 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Applicable Conversion Price pursuant to the terms of Section 4.4.4, such Applicable Conversion Price shall be readjusted to such Applicable Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Applicable Conversion Price provided for in this Section 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Section 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Applicable Conversion Price that would result under the terms of this Section 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to such Applicable Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Applicable Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 4.4.3), without consideration or for a consideration per share less than the Applicable Conversion Price in effect immediately prior to such issuance or deemed issuance, then such Applicable Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) "CP₂" shall mean the Applicable Conversion Price in effect immediately after such issuance or deemed issuance of Additional Shares of Common Stock;

(b) "CP₁" shall mean the Applicable Conversion Price in effect immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock;

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issuance or deemed issuance or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) “B” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued or deemed issued at a price per share equal to CP₁ (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP₁); and

(e) “C” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Section 4.4, the consideration received by the Corporation for the issuance or deemed issuance of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property. Such consideration shall:

- (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;
- (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors (including the Requisite Preferred Directors); and
- (iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors (including the Requisite Preferred Directors).

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Section 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

- (i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision

contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

- (ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Applicable Conversion Price pursuant to the terms of Section 4.4.4, then, upon the final such issuance, such Applicable Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Original Issue Date effect a subdivision of the outstanding Common Stock, the Applicable Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Original Issue Date combine the outstanding shares of Common Stock, the Applicable Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this Section shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Applicable Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Applicable Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing, (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Applicable Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Applicable Conversion Price shall be adjusted pursuant to this Section as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made to the Applicable Conversion Price if the holders of the applicable series of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of such series of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of such series of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of such series of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Section 2.4, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Sections 4.5, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one (1) share of the applicable series of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such

transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Applicable Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the applicable series of Preferred Stock.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Applicable Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than ten (10) days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which such series of Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than ten (10) days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Applicable Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of such series of Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the applicable series of Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the applicable series of Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to such series of Preferred Stock and the Common Stock. Such notice shall be sent at least ten (10) days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 Trigger Events. Upon the earliest of (a) the closing of the sale of shares of Common Stock to the public at a price of at least \$1.7245 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$50,000,000 of gross proceeds to the Corporation and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock Market, the New York Stock Exchange or another exchange or marketplace approved by the Board of Directors (including the approval of the Requisite Preferred Directors) (a “**Qualified IPO**”), (b) immediately prior to the closing of a SPAC Transaction (as defined below) or a “reverse merger” with a publicly traded corporation, pursuant to which the securities held by stockholders of the Corporation will be listed on the New York Stock Exchange or the NASDAQ National Market or another exchange or marketplace approved by the Board of Directors and in connection with which (x) the cash proceeds to the Corporation immediately following the consummation of the SPAC Transaction or reverse merger, as applicable, are at least \$50,000,000, before expenses but after any SPAC stockholder redemptions, and (y) the non-contingent consideration to be received in respect of the Common Stock as determined in the definitive agreement for the SPAC Transaction or reverse merger, as applicable, is at least equal to \$1.7245 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock) or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Series C Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the “**Mandatory Conversion Time**”), then, (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to Section 4.1.1 and (ii) such shares may not be reissued by the Corporation. “**SPAC Transaction**” means a business combination (in the form of a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination) involving the Corporation and a blank check company and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses pursuant to which (A) shares of the Corporation’s capital stock are converted, exchanged for or otherwise disposed for shares of capital stock of such special purpose acquisition company and/or cash, (B) such special acquisition company is obligated to cause the shares of capital stock issued to the stockholders in such business combination to be registered pursuant to an effective registration statement under the Securities Act, on Form S-1 or Form S-4 or any similar or successor form, and (C) the shares of such special acquisition company that are issued in such transaction are listed the New York Stock Exchange or the NASDAQ National Market or another exchange or marketplace approved by the Board of Directors.

5.2 Procedural Requirements. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Section 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Section 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. Redeemed or Otherwise Acquired Shares. Any shares of Preferred Stock that are redeemed, converted or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption, conversion or acquisition.

7. Waiver. Except as otherwise set forth herein, (a) any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the Requisite Holders and (b) at any time more than one (1) series of Preferred Stock is issued and outstanding, any of the rights, powers, preferences and other terms of any series of Preferred Stock set forth herein may be waived on behalf of all holders of such series of Preferred Stock by the affirmative written consent or vote of the holders of at least a majority of the shares of such series of Preferred Stock then outstanding; provided, however, that any such waiver of terms specifically requiring the consent of the Series B Preferred Stock, with respect to the Series B Preferred Stock, shall require, to be effective, the written consent or affirmative vote of the Requisite Series B Holders; provided, further, that any such waiver of terms specifically requiring the consent of the Series C Preferred Stock, with respect to the Series C Preferred Stock, shall require, to be effective, the written consent or affirmative vote of the Requisite Series C Holders.

8. **Notices.** Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: Subject to any additional vote required by this Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws.

SIXTH: Subject to any additional vote required by this Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws. Each director shall be entitled to one (1) vote on each matter presented to the Board of Directors; provided, however, that, so long as the holders of Preferred Stock are entitled to elect any Preferred Director, the affirmative vote the Requisite Preferred Directors shall be required for the authorization by the Board of Directors of any of the matters set forth in Section 5.4 of the Second Amended and Restated Investors' Rights Agreement, dated as of the Original Issue Date, by and among the Corporation and the other parties thereto, as such agreement may be amended from time to time.

SEVENTH: Elections of directors need not be by written ballot unless the Bylaws shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article Tenth shall not (a) adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification or (b) increase the liability of any director of the Corporation with respect to any acts or omissions of such director, officer or agent occurring prior to, such amendment, repeal or modification.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “**Excluded Opportunity**” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee, affiliate or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, the persons referred to in clauses (i) and (ii) are “**Covered Persons**”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation while such Covered Person is performing services in such capacity. Any repeal or modification of this Article Eleventh will only be prospective and will not affect the rights under this Article Eleventh in effect at the time of the occurrence of any actions or omissions to act giving rise to liability. Notwithstanding anything to the contrary contained elsewhere in this Certificate of Incorporation, the affirmative vote of the Requisite Holders, will be required to amend or repeal, or to adopt any provisions inconsistent with this Article Eleventh.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation’s stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation’s Certificate of Incorporation or Bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth

(including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

* * *

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.

4. That this Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Third Amended and Restated Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

[Signature Page Follows]

IN WITNESS WHEREOF, this Fourth Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this 6th day of December, 2023.

By: /s/ Claire Mazumdar
Claire Mazumdar, Chief Executive Officer

SECOND AMENDED AND RESTATED BY-LAWS

of
BICARA THERAPEUTICS INC.

(the "Corporation")

1. Stockholders

(a) Annual Meeting. The annual meeting of stockholders shall be held for the election of directors each year at such place, date and time as shall be designated by the Board of Directors. Any other proper business may be transacted at the annual meeting. If no date for the annual meeting is established or said meeting is not held on the date established as provided above, a special meeting in lieu thereof may be held or there may be action by written consent of the stockholders on matters to be voted on at the annual meeting, and such special meeting or written consent shall have for the purposes of these By-laws or otherwise all the force and effect of an annual meeting.

(b) Special Meetings. Special meetings of stockholders may be called by the Chief Executive Officer, if one is elected, or, if there is no Chief Executive Officer, a President, or by the Board of Directors, but such special meetings may not be called by any other person or persons. The call for the meeting shall state the place, date, hour and purposes of the meeting. Only the purposes specified in the notice of special meeting shall be considered or dealt with at such special meeting.

(c) Notice of Meetings. Whenever stockholders are required or permitted to take any action at a meeting, a notice stating the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present and vote at such meeting, and, in the case of a special meeting, the purpose or purposes of the meeting, shall be given by the Secretary (or other person authorized by these By-laws or by law) not less than ten (10) nor more than sixty (60) days before the meeting to each stockholder entitled to vote thereat and to each stockholder who, under the Certificate of Incorporation or under these By-laws is entitled to such notice. If mailed, notice is given when deposited in the mail, postage prepaid, directed to such stockholder at such stockholder's address as it appears in the records of the Corporation. Without limiting the manner by which notice otherwise may be effectively given to stockholders, any notice to stockholders may be given by electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law (the "DGCL").

If a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place, if any, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken, except that if the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

(d) Quorum. The holders of a majority in interest of all stock issued, outstanding and entitled to vote at a meeting, present in person or represented by proxy, shall constitute a quorum. Any meeting may be adjourned from time to time by a majority of the votes properly cast upon the question, whether or not a quorum is present. The stockholders present at a duly constituted meeting may continue to transact business until adjournment notwithstanding the withdrawal of enough stockholders to reduce the voting shares below a quorum.

(e) Voting and Proxies. Except as otherwise provided by the Certificate of Incorporation or by law, each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of stock held by such stockholder which has voting power upon the matter in question. Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for such stockholder by either written proxy or by a transmission permitted by Section 212(c) of the DGCL, but no proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period or is irrevocable and coupled with an interest. Proxies shall be filed with the Secretary of the meeting, or of any adjournment thereof. Except as otherwise limited therein, proxies shall entitle the persons authorized thereby to vote at any adjournment of such meeting.

(f) Action at Meeting. When a quorum is present, any matter before the meeting shall be decided by vote of the holders of a majority of the shares of stock voting on such matter except where a larger vote is required by law, by the Certificate of Incorporation or by these By-laws. Any election of directors by stockholders shall be determined by a plurality of the votes cast, except where a larger vote is required by law, by the Certificate of Incorporation or by these By-laws. The Corporation shall not directly or indirectly vote any share of its own stock; provided, however, that the Corporation may vote shares which it holds in a fiduciary capacity to the extent permitted by law.

(g) Presiding Officer. Meetings of stockholders shall be presided over by the Chairman of the Board, if one is elected, or in his or her absence, the Vice Chairman of the Board, if one is elected, or if neither is elected or in their absence, a President. The Board of Directors shall have the authority to appoint a temporary presiding officer to serve at any meeting of the stockholders if the Chairman of the Board, the Vice Chairman of the Board or a President is unable to do so for any reason.

(h) Conduct of Meetings. The Board of Directors may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the presiding officer of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the presiding officer of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the Corporation, their duly authorized and constituted proxies or such other persons as the chairman of the meeting shall determine; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the presiding officer of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

(i) Action without a Meeting. Unless otherwise provided in the Certificate of Incorporation, any action required or permitted by law to be taken at any annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation by delivery to its registered office, by hand or by certified mail, return receipt requested, or to the Corporation's principal place of business or to the officer of the Corporation having custody of the minute book. Every written consent shall bear the date of signature and no written consent shall be effective unless, within sixty (60) days of the earliest dated consent delivered pursuant to these By-laws, written consents signed by a sufficient number of stockholders entitled to take action are delivered to the Corporation in the manner set forth in these By-laws. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing.

(j) Stockholder Lists. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing contained in this Section 1(j) shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least ten (10) days prior to the meeting in the manner provided by law. The list shall also be open to the examination of any stockholder during the whole time of the meeting as provided by law.

2. Directors

(a) Powers. The business of the Corporation shall be managed by or under the direction of a Board of Directors who may exercise all the powers of the Corporation except as otherwise provided by law, by the Certificate of Incorporation or by these By-laws. In the event of a vacancy in the Board of Directors, the remaining directors, except as otherwise provided by law, may exercise the powers of the full Board until the vacancy is filled.

(b) Number and Qualification. Unless otherwise provided in the Certificate of Incorporation or in these By-laws, the number of directors which shall constitute the whole board shall be determined from time to time by resolution of the Board of Directors. Directors need not be stockholders.

(c) Vacancies; Reduction of Board. A majority of the directors then in office, although less than a quorum, or a sole remaining Director, may fill vacancies in the Board of Directors occurring for any reason and newly created directorships resulting from any increase in the authorized number of directors. In lieu of filling any vacancy, the Board of Directors may reduce the number of directors.

(d) Tenure. Except as otherwise provided by law, by the Certificate of Incorporation or by these By-laws, directors shall hold office until their successors are elected and qualified or until their earlier resignation or removal. Any director may resign at any time upon notice given in writing or by electronic transmission to the Corporation. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

(e) Removal. To the extent permitted by law, a director may be removed from office with or without cause by vote of the holders of a majority of the shares of stock entitled to vote in the election of directors.

(f) Meetings. Regular meetings of the Board of Directors may be held without notice at such time, date and place as the Board of Directors may from time to time determine. Special meetings of the Board of Directors may be called, orally or in writing, by the Chief Executive Officer, if one is elected, or, if there is no Chief Executive Officer, the President, or by two or more Directors, designating the time, date and place thereof. Directors may participate in meetings of the Board of Directors by means of conference telephone or other communications equipment by means of which all directors participating in the meeting can hear each other, and participation in a meeting in accordance herewith shall constitute presence in person at such meeting.

(g) Notice of Meetings. Notice of the time, date and place of all special meetings of the Board of Directors shall be given to each director by the Secretary, or Assistant Secretary, or in case of the death, absence, incapacity or refusal of such persons, by the officer or one of the directors calling the meeting. Notice shall be given to each director in person, by telephone, or by facsimile, electronic mail or other form of electronic communications, sent to such director's business or home address at least twenty-four (24) hours in advance of the meeting, or by written notice mailed to such director's business or home address at least forty-eight (48) hours in advance of the meeting.

(h) Quorum. At any meeting of the Board of Directors, the greater of (a) a majority of the directors then in office at the time quorum is to be determined and (b) one-third of the total number of directors fixed pursuant to Section 2(b) of these By-laws shall constitute a quorum for the transaction of business. Less than a quorum may adjourn any meeting from time to time and the meeting may be held as adjourned without further notice.

(i) Action at Meeting. At any meeting of the Board of Directors at which a quorum is present, unless otherwise provided in the following sentence, a majority of the directors present may take any action on behalf of the Board of Directors, unless a larger number is required by law, by the Certificate of Incorporation or by these By-laws. So long as there are two (2) or fewer Directors, any action to be taken by the Board of Directors shall require the approval of all Directors.

(j) Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors may be taken without a meeting if all members of the Board of Directors consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the records of the meetings of the Board of Directors. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

(k) Committees. The Board of Directors may, by resolution passed by a majority of the whole Board of Directors, establish one or more committees, each committee to consist of one or more directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

Any such committee, to the extent permitted by law and to the extent provided in the resolution of the Board of Directors, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to the following: (i) approving or adopting, or recommending to the stockholders, any action or matter expressly required by the DGCL to be submitted to stockholders for approval or (ii) adopting, amending or repealing any provision of these By-laws.

Except as the Board of Directors may otherwise determine, any such committee may make rules for the conduct of its business, but in the absence of such rules its business shall be conducted so far as possible in the same manner as is provided in these By-laws for the Board of Directors. All members of such committees shall hold their committee offices at the pleasure of the Board of Directors, and the Board may abolish any committee at any time.

3. Officers

(a) Enumeration. The officers of the Corporation shall consist of one or more Presidents (who, if there is more than one, shall be referred to as Co-Presidents), a Treasurer, a Secretary, and such other officers, including, without limitation, a Chief Executive Officer and one or more Vice Presidents (including Executive Vice Presidents or Senior Vice Presidents), Assistant Vice Presidents, Assistant Treasurers and Assistant Secretaries, as the Board of Directors may determine. The Board of Directors may elect from among its members a Chairman of the Board and a Vice Chairman of the Board.

(b) Election. The Presidents, Treasurer and Secretary shall be elected annually by the Board of Directors at their first meeting following the annual meeting of stockholders. Other officers may be chosen by the Board of Directors at such meeting or at any other meeting.

(c) Qualification. No officer need be a stockholder or Director. Any two or more offices may be held by the same person. Any officer may be required by the Board of Directors to give bond for the faithful performance of such officer's duties in such amount and with such sureties as the Board of Directors may determine.

(d) Tenure. Except as otherwise provided by the Certificate of Incorporation or by these By-laws, each of the officers of the Corporation shall hold office until the first meeting of the Board of Directors following the next annual meeting of stockholders and until such officer's successor is elected and qualified or until such officer's earlier resignation or removal. Any officer may resign by delivering his or her written resignation to the Corporation, and such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

(e) Removal. The Board of Directors may remove any officer with or without cause by a vote of a majority of the directors then in office.

(f) Vacancies. Any vacancy in any office may be filled for the unexpired portion of the term by the Board of Directors.

(g) Chairman of the Board and Vice Chairman. Unless otherwise provided by the Board of Directors, the Chairman of the Board of Directors, if one is elected, shall preside, when present, at all meetings of the stockholders and the Board of Directors. The Chairman of the Board shall have such other powers and shall perform such duties as the Board of Directors may from time to time designate.

Unless otherwise provided by the Board of Directors, in the absence of the Chairman of the Board, the Vice Chairman of the Board, if one is elected, shall preside, when present, at all meetings of the stockholders and the Board of Directors. The Vice Chairman of the Board shall have such other powers and shall perform such duties as the Board of Directors may from time to time designate.

(h) Chief Executive Officer. The Chief Executive Officer, if one is elected, shall have such powers and shall perform such duties as the Board of Directors may from time to time designate.

(i) Presidents. The Presidents shall, subject to the direction of the Board of Directors, each have general supervision and control of the Corporation's business and any action that would typically be taken by a President may be taken by any Co-President. If there is no Chairman of the Board or Vice Chairman of the Board, a President shall preside, when present, at all meetings of stockholders and the Board of Directors. The Presidents shall have such other powers and shall perform such duties as the Board of Directors may from time to time designate.

(j) Vice Presidents and Assistant Vice Presidents. Any Vice President (including any Executive Vice President or Senior Vice President) and any Assistant Vice President shall have such powers and shall perform such duties as the Board of Directors may from time to time designate.

(k) Treasurer and Assistant Treasurers. The Treasurer shall, subject to the direction of the Board of Directors, have general charge of the financial affairs of the Corporation and shall cause to be kept accurate books of account. The Treasurer shall have custody of all funds, securities, and valuable documents of the Corporation, except as the Board of Directors may otherwise provide. The Treasurer shall have such other powers and shall perform such duties as the Board of Directors may from time to time designate.

Any Assistant Treasurer shall have such powers and perform such duties as the Board of Directors may from time to time designate.

(l) Secretary and Assistant Secretaries. The Secretary shall record the proceedings of all meetings of the stockholders and the Board of Directors (including committees of the Board) in books kept for that purpose. In the absence of the Secretary from any such meeting an Assistant Secretary, or if such person is absent, a temporary secretary chosen at the meeting, shall record the proceedings thereof. The Secretary shall have charge of the stock ledger (which may, however, be kept by any transfer or other agent of the Corporation) and shall have such other duties and powers as may be designated from time to time by the Board of Directors.

Any Assistant Secretary shall have such powers and perform such duties as the Board of Directors may from time to time designate.

(m) Other Powers and Duties. Subject to these By-laws, each officer of the Corporation shall have in addition to the duties and powers specifically set forth in these By-laws, such duties and powers as are customarily incident to such officer's office, and such duties and powers as may be designated from time to time by the Board of Directors.

4. Capital Stock

(a) Certificates of Stock. Each stockholder shall be entitled to a certificate of the capital stock of the Corporation in such form as may from time to time be prescribed by the Board of Directors. Such certificate shall be signed by, or in the name of, the Corporation by any two (2) authorized officers of the Corporation. Such signatures may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed on such certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the time of its issue. Every certificate for shares of stock which are subject to any restriction on transfer and every certificate issued when the Corporation is authorized to issue more than one class or series of stock shall contain such legend with respect thereto as is required by law. The Corporation shall be permitted to issue fractional shares.

(b) Transfers. Subject to any restrictions on transfer including pursuant to clause (f) below, shares of stock may be transferred on the books of the Corporation by the surrender to the Corporation or its transfer agent of the certificate therefor properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, and with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require.

(c) Record Holders. Except as may otherwise be required by law, by the Certificate of Incorporation or by these By-laws, the Corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect thereto, regardless of any transfer, pledge or other disposition of such stock, until the shares have been transferred on the books of the Corporation in accordance with the requirements of these By-laws.

It shall be the duty of each stockholder to notify the Corporation of such stockholder's post office address.

(d) Record Date. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or to consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not precede the date on which it is established, and which shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting, more than ten (10) days after the date on which the record date for stockholder consent without a meeting is established, nor more than sixty (60) days prior to any other action. In such case only stockholders of record on such record date shall be so entitled notwithstanding any transfer of stock on the books of the Corporation after the record date.

If no record date is fixed, (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held, (ii) the record date for determining stockholders entitled to consent to corporate action in writing without a meeting, when no prior action by the Board of Directors is necessary, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in this state, to its principal place of business, or to an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded, and (iii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

(e) Lost Certificates. The Corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or his legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

(f) Restrictions on Transfer.

(i) No holder of any of the shares of stock of the Corporation may sell, transfer, assign, pledge, or otherwise dispose of or encumber any of the shares of stock of the Corporation or any right or interest therein, whether voluntarily or by operation of law, or by gift or otherwise (each, a "Transfer") without the prior written consent of the Corporation, upon duly authorized action of its Board of Directors. The Corporation may withhold consent for any legitimate corporate purpose, as determined by the Board of Directors.

(ii) If a stockholder desires to Transfer any shares, then the stockholder will first give written notice to the Corporation. The notice must name the proposed transferee and state the number of shares to be transferred, the proposed consideration, and all other terms and conditions of the proposed transfer. Any shares proposed to be transferred to which Transfer the Corporation has consented pursuant to paragraph (b) of this Section will first be subject to the Corporation's right of first refusal located in Section 4(g) of these By-laws.

(iii) At the option of the Corporation, the stockholder will be obligated to pay to the Corporation a reasonable transfer fee related to the costs and time of the Corporation and its legal and other advisors related to any proposed Transfer.

(iv) Any Transfer, or purported Transfer, of shares not made in strict compliance with this Section will be null and void, will not be recorded on the books of the Corporation and will not be recognized by the Corporation. Transfers of record of shares of stock of the Corporation will be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by certificate, upon the surrender of a properly endorsed certificate or certificates for a like number of shares.

(v) The restriction on Transfer set forth in this Section 4(f) will not apply to the Transfer of shares of Preferred Stock or to the Transfer of any shares of Common Stock issued upon the conversion of any shares of Preferred Stock.

(vi) The restriction on Transfer set forth in this Section 4(f) will terminate upon the date securities of the Corporation are first offered to the public pursuant to a registration statement filed with, and declared effective by, the SEC under the Securities Act of 1933, as amended (the "1933 Act").

(vii) The certificates representing shares of Common Stock of the Corporation will bear on their face the following legend so long as the foregoing Transfer restrictions are in effect:

"THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A TRANSFER RESTRICTION, AS PROVIDED IN THE BY-LAWS OF THE CORPORATION."

(g) Right of First Refusal. No stockholder will Transfer any of the shares of stock of the Corporation, except by a Transfer that meets the requirements set forth in this 4(g), in addition to any other restrictions or requirements set forth under applicable law or these By-laws:

(i) If the stockholder desires to Transfer any of his or her shares of stock, then the stockholder must first give written notice thereof to the Corporation. The notice must name the proposed transferee and state the number of shares to be transferred, the proposed consideration, and all other terms and conditions of the proposed transfer.

(ii) For 30 days following receipt of such notice, the Corporation has the option to purchase up to all the shares specified in the notice at the price and upon the terms set forth in such notice; provided, however, that, with the consent of the stockholder, the Corporation has the option to purchase a lesser portion of the shares specified in said notice at the price and upon the terms set forth therein. In the event of a gift, property settlement or other Transfer in which the proposed transferee is not paying the full price for the shares, and that is not otherwise exempted from the provisions of this Section, the price will be deemed to be the fair market value of the stock at such time as determined in good faith by the Board of Directors. In the event the Corporation elects to purchase all of the shares or, with consent of the stockholder, a lesser portion of the shares, it will give written notice to the transferring stockholder of its election and settlement for said shares will be made as provided below in paragraph (d) of this Section.

(iii) The Corporation may assign its rights hereunder.

(iv) In the event the Corporation and/or its assignee(s) elect to acquire any of the shares of the transferring stockholder as specified in said transferring stockholder's notice, the Secretary of the Corporation will so notify the transferring stockholder and settlement thereof will be made in cash within 30 days after the Secretary of the Corporation receives said transferring stockholder's notice; provided that if the terms of payment set forth in said transferring stockholder's notice were other than cash against delivery, the Corporation and/or its assignee(s) will pay for said shares on the same terms and conditions set forth in said transferring stockholder's notice.

(v) In the event the Corporation and/or its assignees(s) do not elect to acquire all of the shares specified in the transferring stockholder's notice, said transferring stockholder may, subject to the Corporation's approval and all other restrictions on Transfer located in Section 4(f) of these By-laws, within the 60-day period following the expiration or waiver of the option rights granted to the Corporation and/or its assignees(s) herein, Transfer the shares specified in said transferring stockholder's notice that were not acquired by the Corporation and/or its assignees(s) as specified in said transferring stockholder's notice. All shares so sold by said transferring stockholder will continue to be subject to the provisions of this Section 4(g) in the same manner as before said Transfer.

(vi) Anything to the contrary contained herein notwithstanding, the following transactions are exempt from the right of first refusal contained in this Section 4(g):

(A) A stockholder's Transfer of any or all shares held either during such stockholder's lifetime or on death by will or intestacy to such stockholder's immediate family or to any custodian or trustee for the account of such stockholder or such stockholder's immediate family or to any limited partnership or limited liability company of which the stockholder, members of such stockholder's immediate family or any trust for the account of such stockholder or such stockholder's immediate family will be the general or limited partner(s) of such partnership or the controlling member(s) of such limited liability company. "Immediate family" as used herein means spouse, lineal descendant, father, mother, brother, or sister of the stockholder making such Transfer;

(B) A stockholder's bona fide pledge or mortgage of any shares with a commercial lending institution, provided that any subsequent Transfer of said shares by said institution will be conducted in the manner set forth in this Section 4(g);

(C) A stockholder's Transfer of any or all of such stockholder's shares to the Corporation or to any other stockholder of the Corporation;

(D) A stockholder's Transfer of any or all of such stockholder's shares to a person who, at the time of such Transfer, is an officer or director of the Corporation;

(E) A corporate stockholder's Transfer of any or all of its shares pursuant to and in accordance with the terms of any merger, consolidation, reclassification of shares or capital reorganization of the corporate stockholder, or pursuant to a sale of all or substantially all of the stock or assets of a corporate stockholder; or

(F) A stockholder's Transfer of shares of Preferred Stock of the Corporation (or any shares of Common Stock issued upon conversion thereof).

In any such case, the transferee, assignee, or other recipient will receive and hold such stock subject to the provisions of this Section and any other restrictions set forth in these By-laws, and there will be no further Transfer of such stock except in accord with this Section and the other provisions of these By-laws.

(vii) The provisions of this Section 4(g) may be waived with respect to any Transfer either by the Corporation, upon duly authorized action of its Board of Directors, or by the stockholders, upon the express written consent of the owners of a majority of the voting power of the Corporation (excluding the votes represented by those shares to be transferred by the transferring stockholder). This Section 4(g) may be amended or repealed either by a duly authorized action of the Board of Directors or by the stockholders, upon the express written consent of the owners of a majority of the voting power of the Corporation.

(viii) Any Transfer, or purported Transfer, of securities of the Corporation will be null and void unless the terms, conditions, and provisions of this Section 4(g) are strictly observed and followed.

(ix) The foregoing right of first refusal will terminate upon the date securities of the Corporation are first offered to the public pursuant to a registration statement filed with, and declared effective by, the SEC under the Securities Act of 1933, as amended.

(x) The certificates representing shares of Common Stock of the Corporation that are subject to the right of first refusal contained in this Section 4(g) will bear on their face the following legend so long as the foregoing right of first refusal remains in effect:

“THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A RIGHT OF FIRST REFUSAL OPTION IN FAVOR OF THE CORPORATION AND/OR ITS ASSIGNEE(S), AS PROVIDED IN THE BY-LAWS OF THE CORPORATION.”

(xi) To the extent this Section conflicts with any written agreements between the Corporation and the stockholder attempting to Transfer shares, such agreement will control.

5. Indemnification

(a) Definitions. For purposes of this Section 5:

(i) “Corporate Status” describes the status of a person who is serving or has served (A) as a Director of the Corporation, (B) as an Officer of the Corporation, (C) as a Non-Officer Employee of the Corporation, or (D) as a director, partner, trustee, officer, employee or agent of any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan, foundation, association, organization or other legal entity for which such person is or was serving at the request of the Corporation. For purposes of this Section 5(a)(i), a Director, Officer or Non-Officer Employee of the Corporation who is serving or has served as a director, partner, trustee, officer, employee or agent of a Subsidiary shall be deemed to be serving at the request of the Corporation. Notwithstanding the foregoing, “Corporate Status” shall not include the status of a person who is serving or has served as a director, officer, employee or agent of a constituent corporation absorbed in a merger or consolidation transaction with the Corporation with respect to such person’s activities prior to said transaction, unless specifically authorized by the Board of Directors or the stockholders of the Corporation;

(ii) “Director” means any person who serves or has served the Corporation as a director on the Board of Directors of the Corporation;

(iii) “Disinterested Director” means, with respect to each Proceeding in respect of which indemnification is sought hereunder, a Director of the Corporation who is not and was not a party to such Proceeding;

(iv) “Expenses” means all reasonable attorneys fees, retainers, court costs, transcript costs, fees of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), travel expenses, duplicating costs, printing and binding costs, costs of preparation of demonstrative evidence and other courtroom presentation aids and devices, costs incurred in connection with document review, organization, imaging and computerization, telephone charges, postage, delivery service fees, and all other disbursements, costs or expenses of the type customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, settling or otherwise participating in, a Proceeding;

(v) “Liabilities” means judgments, damages, liabilities, losses, penalties, excise taxes, fines and amounts paid in settlement;

(vi) “Non-Officer Employee” means any person who serves or has served as an employee or agent of the Corporation, but who is not or was not a Director or Officer;

(vii) "Officer" means any person who serves or has served the Corporation as an officer of the Corporation appointed by the Board of Directors of the Corporation;

(viii) "Proceeding" means any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, inquiry, investigation, administrative hearing or other proceeding, whether civil, criminal, administrative, arbitrative or investigative; and

(ix) "Subsidiary" shall mean any corporation, partnership, limited liability company, joint venture, trust or other entity of which the Corporation owns (either directly or through or together with another Subsidiary of the Corporation) either (i) a general partner, managing member or other similar interest or (ii) (A) 50% or more of the voting power of the voting capital equity interests of such corporation, partnership, limited liability company, joint venture or other entity, or (B) 50% or more of the outstanding voting capital stock or other voting equity interests of such corporation, partnership, limited liability company, joint venture or other entity.

(b) Indemnification of Directors and Officers. Subject to the operation of Section 5(d) of these By-laws, each Director and Officer shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), and to the extent authorized in subsections (i) through (iv) of this Section 5(b).

(i) Actions, Suits and Proceedings Other than By or In the Right of the Corporation. Each Director and Officer shall be indemnified and held harmless by the Corporation against any and all Expenses and Liabilities that are incurred or paid by such Director or Officer or on such Director's or Officer's behalf in connection with any Proceeding or any claim, issue or matter therein (other than an action by or in the right of the Corporation), which such Director or Officer is, or is threatened to be made, a party to or participant in by reason of such Director's or Officer's Corporate Status, if such Director or Officer acted in good faith and in a manner such Director or Officer reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful.

(ii) Actions, Suits and Proceedings By or In the Right of the Corporation. Each Director and Officer shall be indemnified and held harmless by the Corporation against any and all Expenses that are incurred by such Director or Officer or on such Director's or Officer's behalf in connection with any Proceeding or any claim, issue or matter therein by or in the right of the Corporation, which such Director or Officer is, or is threatened to be made, a party to or participant in by reason of such Director's or Officer's Corporate Status, if such Director or Officer acted in good faith and in a manner such Director or Officer reasonably believed to be in or not opposed to the best interests of the Corporation; provided, however, that no indemnification shall be made under this Section 5(b)(ii) in respect of any claim, issue or matter as to which such Director or

Officer shall have been finally adjudged by a court of competent jurisdiction to be liable to the Corporation, unless, and only to the extent that, the Court of Chancery or another court in which such Proceeding was brought shall determine upon application that, despite adjudication of liability, but in view of all the circumstances of the case, such Director or Officer is fairly and reasonably entitled to indemnification for such Expenses that such court deems proper.

(iii) Survival of Rights. The rights of indemnification provided by this Section 5(b) shall continue as to a Director or Officer after he or she has ceased to be a Director or Officer and shall inure to the benefit of his or her heirs, executors, administrators and personal representatives.

(iv) Actions by Directors or Officers. Notwithstanding the foregoing, the Corporation shall indemnify any Director or Officer seeking indemnification in connection with a Proceeding initiated by such Director or Officer only if such Proceeding (including any parts of such Proceeding not initiated by such Director or Officer) was authorized in advance by the Board of Directors of the Corporation, unless such Proceeding was brought to enforce such Officer's or Director's rights to indemnification or, in the case of Directors, advancement of Expenses under these By-laws in accordance with the provisions set forth herein.

(c) Indemnification of Non-Officer Employees. Subject to the operation of Section 5(d) of these By-laws, each Non-Officer Employee may, in the discretion of the Board of Directors of the Corporation, be indemnified by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against any or all Expenses and Liabilities that are incurred by such Non-Officer Employee or on such Non-Officer Employee's behalf in connection with any threatened, pending or completed Proceeding, or any claim, issue or matter therein, which such Non-Officer Employee is, or is threatened to be made, a party to or participant in by reason of such Non-Officer Employee's Corporate Status, if such Non-Officer Employee acted in good faith and in a manner such Non-Officer Employee reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The rights of indemnification provided by this Section 5(c) shall exist as to a Non-Officer Employee after he or she has ceased to be a Non-Officer Employee and shall inure to the benefit of his or her heirs, personal representatives, executors and administrators. Notwithstanding the foregoing, the Corporation may indemnify any Non-Officer Employee seeking indemnification in connection with a Proceeding initiated by such Non-Officer Employee only if such Proceeding was authorized in advance by the Board of Directors of the Corporation.

(d) Determination. Unless ordered by a court, no indemnification shall be provided pursuant to this Section 5 to a Director, to an Officer or to a Non-Officer Employee unless a determination shall have been made that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal Proceeding, such person had no reasonable cause to believe his or her conduct was unlawful. Such determination shall be made by (i) a majority vote of the Disinterested Directors, even though less than a quorum of the Board of Directors, (ii) a committee comprised of Disinterested Directors, such committee having been designated by a majority vote of the Disinterested Directors (even though less than a quorum), (iii) if there are no such Disinterested Directors, or if a majority of Disinterested Directors so directs, by independent legal counsel in a written opinion, or (iv) by the stockholders of the Corporation.

(e) Advancement of Expenses to Directors Prior to Final Disposition.

(i) The Corporation shall advance all Expenses incurred by or on behalf of any Director in connection with any Proceeding in which such Director is involved by reason of such Director's Corporate Status within thirty (30) days after the receipt by the Corporation of a written statement from such Director requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Director and shall be preceded or accompanied by an undertaking by or on behalf of such Director to repay any Expenses so advanced if it shall ultimately be determined that such Director is not entitled to be indemnified against such Expenses. Notwithstanding the foregoing, the Corporation shall advance all Expenses incurred by or on behalf of any Director seeking advancement of expenses hereunder in connection with a Proceeding initiated by such Director only if such Proceeding (including any parts of such Proceeding not initiated by such Director) was (A) authorized by the Board of Directors of the Corporation, or (B) brought to enforce such Director's rights to indemnification or advancement of Expenses under these By-laws.

(ii) If a claim for advancement of Expenses hereunder by a Director is not paid in full by the Corporation within thirty (30) days after receipt by the Corporation of documentation of Expenses and the required undertaking, such Director may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim and if successful in whole or in part, such Director shall also be entitled to be paid the expenses of prosecuting such claim. The failure of the Corporation (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of such advancement of Expenses under this Section 5 shall not be a defense to an action brought by a Director for recovery of the unpaid amount of an advancement claim and shall not create a presumption that such advancement is not permissible. The burden of proving that a Director is not entitled to an advancement of expenses shall be on the Corporation.

(iii) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Director has not met any applicable standard for indemnification set forth in the DGCL.

(f) Advancement of Expenses to Officers and Non-Officer Employees Prior to Final Disposition.

(i) The Corporation may, at the discretion of the Board of Directors of the Corporation, advance any or all Expenses incurred by or on behalf of any Officer or any Non-Officer Employee in connection with any Proceeding in which such person is involved by reason of his or her Corporate Status as an Officer or Non-Officer Employee

upon the receipt by the Corporation of a statement or statements from such Officer or Non-Officer Employee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Officer or Non-Officer Employee and shall be preceded or accompanied by an undertaking by or on behalf of such person to repay any Expenses so advanced if it shall ultimately be determined that such Officer or Non-Officer Employee is not entitled to be indemnified against such Expenses.

(ii) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Officer or Non-Officer Employee has not met any applicable standard for indemnification set forth in the DGCL.

(g) Contractual Nature of Rights.

(i) The provisions of this Section 5 shall be deemed to be a contract between the Corporation and each Director and Officer entitled to the benefits hereof at any time while this Section 5 is in effect, in consideration of such person's past or current and any future performance of services for the Corporation. Neither amendment, repeal or modification of any provision of this Section 5 nor the adoption of any provision of the Certificate of Incorporation inconsistent with this Section 5 shall eliminate or reduce any right conferred by this Section 5 in respect of any act or omission occurring, or any cause of action or claim that accrues or arises or any state of facts existing, at the time of or before such amendment, repeal, modification or adoption of an inconsistent provision (even in the case of a proceeding based on such a state of facts that is commenced after such time), and all rights to indemnification and advancement of Expenses granted herein or arising out of any act or omission shall vest at the time of the act or omission in question, regardless of when or if any proceeding with respect to such act or omission is commenced. The rights to indemnification and to advancement of expenses provided by, or granted pursuant to, this Section 5 shall continue notwithstanding that the person has ceased to be a director or officer of the Corporation and shall inure to the benefit of the estate, heirs, executors, administrators, legatees and distributees of such person.

(ii) If a claim for indemnification hereunder by a Director or Officer is not paid in full by the Corporation within sixty (60) days after receipt by the Corporation of a written claim for indemnification, such Director or Officer may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim, and if successful in whole or in part, such Director or Officer shall also be entitled to be paid the expenses of prosecuting such claim. The failure of the Corporation (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of such indemnification under this Section 5 shall not be a defense to an action brought by a Director or Officer for recovery of the unpaid amount of an indemnification claim and shall not create a presumption that such indemnification is not permissible. The burden of proving that a Director or Officer is not entitled to indemnification shall be on the Corporation.

(iii) In any suit brought by a Director or Officer to enforce a right to indemnification hereunder, it shall be a defense that such Director or Officer has not met any applicable standard for indemnification set forth in the DGCL.

(h) Non-Exclusivity of Rights. The rights to indemnification and advancement of Expenses set forth in this Section 5 shall not be exclusive of any other right which any Director, Officer, or Non-Officer Employee may have or hereafter acquire under any statute, provision of the Certificate or these By-laws, agreement, vote of stockholders or Disinterested Directors or otherwise.

(i) Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any Director, Officer or Non-Officer Employee against any liability of any character asserted against or incurred by the Corporation or any such Director, Officer or Non-Officer Employee, or arising out of any such person's Corporate Status, whether or not the Corporation would have the power to indemnify such person against such liability under the DGCL or the provisions of this Section 5.

(j) Other Indemnification. The Corporation's obligation, if any, to indemnify or provide advancement of Expenses to any person under this Section 5 as a result of such person serving, at the request of the Corporation, as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount such person may collect as indemnification or advancement of Expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or enterprise (the "Primary Indemnitor"). Any indemnification or advancement of Expenses under this Section 5 owed by the Corporation as a result of a person serving, at the request of the Corporation, as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall only be in excess of, and shall be secondary to, the indemnification or advancement of Expenses available from the applicable Primary Indemnitor(s) and any applicable insurance policies.

6. Miscellaneous Provisions

(a) Fiscal Year. Except as otherwise determined by the Board of Directors, the fiscal year of the Corporation shall end on December 31 of each year.

(b) Seal. The Board of Directors shall have power to adopt and alter the seal of the Corporation.

(c) Execution of Instruments. Subject to any limitations which may be set forth in a resolution of the Board of Directors, all deeds, leases, transfers, contracts, bonds, notes and other obligations to be entered into by the Corporation in the ordinary course of its business without director action may be executed on behalf of the Corporation by, a President, or by any other officer, employee or agent of the Corporation as the Board of Directors may authorize.

(d) Voting of Securities. Unless the Board of Directors otherwise provides, a President, any Vice President or the Treasurer may waive notice of and act on behalf of this Corporation, or appoint another person or persons to act as proxy or attorney in fact for this Corporation with or without discretionary power and/or power of substitution, at any meeting of stockholders or shareholders of any other corporation or organization, any of whose securities are held by this Corporation.

(e) Resident Agent. The Board of Directors may appoint a resident agent upon whom legal process may be served in any action or proceeding against the Corporation.

(f) Corporate Records. The original or attested copies of the Certificate of Incorporation, By-laws and records of all meetings of the incorporators, stockholders and the Board of Directors and the stock and transfer records, which shall contain the names of all stockholders, their record addresses and the amount of stock held by each, shall be kept at the principal office of the Corporation, at the office of its counsel, or at an office of its transfer agent.

(g) Certificate of Incorporation. All references in these By-laws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the Corporation, as amended and in effect from time to time.

(h) Amendments. These By-laws may be altered, amended or repealed, and new By-laws may be adopted, by the stockholders or by the Board of Directors; provided, that (a) the Board of Directors may not alter, amend or repeal any provision of these By-laws which by law, by the Certificate of Incorporation or by these By-laws requires action by the stockholders and (b) any alteration, amendment or repeal of these By-laws by the Board of Directors and any new By-law adopted by the Board of Directors may be altered, amended or repealed by the stockholders.

(i) Waiver of Notice. Whenever notice is required to be given under any provision of these By-laws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any meeting needs to be specified in any written waiver or any waiver by electronic transmission.

Adopted March 2, 2023.

BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the "Plan"). The purpose of the Plan is to encourage and enable the officers, employees, directors, Consultants and other key persons of Bicara Therapeutics Inc., a Delaware corporation (including any successor entity, the "Company") and its Affiliates, upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its business, to acquire a proprietary interest in the Company.

The following terms shall be defined as set forth below:

"*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

"*Award*" or "*Awards*," except where referring to a particular category of grant under the Plan, shall include Incentive Stock Options, Non-Qualified Stock Options, Restricted Stock Awards, Unrestricted Stock Awards, Restricted Stock Units or any combination of the foregoing.

"*Award Agreement*" means a written or electronic agreement setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Agreement may contain terms and conditions in addition to those set forth in the Plan; *provided, however*, in the event of any conflict in the terms of the Plan and the Award Agreement, the terms of the Plan shall govern.

"*Board*" means the Board of Directors of the Company.

"*Cause*" shall have the meaning as set forth in the Award Agreement(s). In the case that any Award Agreement does not contain a definition of "Cause," it shall mean (i) the grantee's dishonest statements or acts with respect to the Company or any Affiliate of the Company, or any current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) the grantee's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the grantee's failure to perform his assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to the grantee by the Company; (iv) the grantee's gross negligence, willful misconduct or insubordination with respect to the Company or any Affiliate of the Company; or (v) the grantee's material violation of any provision of any agreement(s) between the grantee and the Company relating to noncompetition, nonsolicitation, nondisclosure and/or assignment of inventions.

"*Chief Executive Officer*" means the Chief Executive Officer of the Company or, if there is no Chief Executive Officer, then the President of the Company.

“Code” means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

“Committee” means the Committee of the Board referred to in Section 2.

“Consultant” means any natural person that provides bona fide services to the Company (including an Affiliate), and such services are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company’s securities.

“Disability” means “disability” as defined in Section 422(c) of the Code.

“Effective Date” means the date on which the Plan is adopted as set forth on the final page of the Plan.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

“Fair Market Value” of the Stock on any given date means the fair market value of the Stock determined in good faith by the Committee based on the reasonable application of a reasonable valuation method not inconsistent with Section 409A of the Code. If the Stock is admitted to trade on a national securities exchange, the determination shall be made by reference to the closing price reported on such exchange. If there is no closing price for such date, the determination shall be made by reference to the last date preceding such date for which there is a closing price. If the date for which Fair Market Value is determined is the first day when trading prices for the Stock are reported on a national securities exchange, the Fair Market Value shall be the “Price to the Public” (or equivalent) set forth on the cover page for the final prospectus relating to the Company’s Initial Public Offering.

“Good Reason” shall have the meaning as set forth in the Award Agreement(s). In the case that any Award Agreement does not contain a definition of “Good Reason,” it shall mean (i) a material diminution in the grantee’s base salary except for across-the-board salary reductions similarly affecting all or substantially all similarly situated employees of the Company or (ii) a change of more than 50 miles in the geographic location at which the grantee provides services to the Company, so long as the grantee provides at least 90 days notice to the Company following the initial occurrence of any such event and the Company fails to cure such event within 30 days thereafter.

“Grant Date” means the date that the Committee designates in its approval of an Award in accordance with applicable law as the date on which the Award is granted, which date may not precede the date of such Committee approval.

“Holder” means, with respect to an Award or any Shares, the Person holding such Award or Shares, including the initial recipient of the Award or any Permitted Transferee.

“Incentive Stock Option” means any Stock Option designated and qualified as an “incentive stock option” as defined in Section 422 of the Code.

“*Initial Public Offering*” means the consummation of the first firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act covering the offer and sale by the Company of its equity securities, as a result of or following which the Stock shall be publicly held.

“*Non-Qualified Stock Option*” means any Stock Option that is not an Incentive Stock Option.

“*Option*” or “*Stock Option*” means any option to purchase shares of Stock granted pursuant to Section 5.

“*Permitted Transferees*” shall mean any of the following to whom a Holder may transfer Shares hereunder (as set forth in Section 9(a)(ii)(A)): the Holder’s child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the Holder’s household (other than a tenant or employee), a trust in which these persons have more than fifty percent of the beneficial interest, a foundation in which these persons control the management of assets, and any other entity in which these persons own more than fifty percent of the voting interests; *provided, however*, that any such trust does not require or permit distribution of any Shares during the term of the Award Agreement unless subject to its terms. Upon the death of the Holder, the term Permitted Transferees shall also include such deceased Holder’s estate, executors, administrators, personal representatives, heirs, legatees and distributees, as the case may be.

“*Person*” shall mean any individual, corporation, partnership (limited or general), limited liability company, limited liability partnership, association, trust, joint venture, unincorporated organization or any similar entity.

“*Restricted Stock Award*” means Awards granted pursuant to Section 6 and “*Restricted Stock*” means Shares issued pursuant to such Awards.

“*Restricted Stock Unit*” means an Award of phantom stock units to a grantee, which may be settled in cash or Shares as determined by the Committee, pursuant to Section 8.

“*Sale Event*” means the consummation of (i) the dissolution or liquidation of the Company, (ii) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (iii) a merger, reorganization or consolidation pursuant to which the holders of the Company’s outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the surviving or resulting entity (or its ultimate parent, if applicable), (iv) the acquisition of all or a majority of the outstanding voting stock of the Company in a single transaction or a series of related transactions by a Person or group of Persons, or (v) any other acquisition of the business of the Company, as determined by the Board; *provided, however*, that the Company’s Initial Public Offering, any subsequent public offering or another capital raising event, or a merger effected solely to change the Company’s domicile shall not constitute a “Sale Event.”

“*Section 409A*” means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

“*Securities Act*” means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

“*Service Relationship*” means any relationship as a full-time employee, part-time employee, director or other key person (including Consultants) of the Company or any Affiliate or any successor entity (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual’s status changes from full-time employee to part-time employee or Consultant).

“*Shares*” means shares of Stock.

“*Stock*” means the Common Stock, par value **\$0.0001** per share, of the Company.

“*Subsidiary*” means any corporation or other entity (other than the Company) in which the Company has more than a 50 percent interest, either directly or indirectly.

“*Ten Percent Owner*” means an employee who owns or is deemed to own (by reason of the attribution rules of Section 424(d) of the Code) more than 10 percent of the combined voting power of all classes of stock of the Company or any parent of the Company or any Subsidiary.

“*Termination Event*” means, except as set forth in an Award Agreement, the termination of the Award recipient’s Service Relationship with the Company and its Affiliates for any reason whatsoever, regardless of the circumstances thereof, and including, without limitation, upon death, disability, retirement, discharge or resignation for any reason, whether voluntarily or involuntarily. The following shall not constitute a Termination Event: (i) a transfer to the service of the Company from an Affiliate or from the Company to an Affiliate, or from one Subsidiary to another Affiliate or (ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Committee, if the individual’s right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Committee otherwise so provides in writing.

“*Unrestricted Stock Award*” means any Award granted pursuant to Section 7 and “*Unrestricted Stock*” means Shares issued pursuant to such Awards.

SECTION 2. ADMINISTRATION OF PLAN; COMMITTEE AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

(a) Administration of Plan. The Plan shall be administered by the Board, or at the discretion of the Board, by a committee of the Board, comprised of not less than two directors. All references herein to the “Committee” shall be deemed to refer to the group then responsible for administration of the Plan at the relevant time (i.e., either the Board of Directors or a committee or committees of the Board, as applicable).

(b) Powers of Committee. The Committee shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

- (i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the amount, if any, of Incentive Stock Options, Non-Qualified Stock Options, Restricted Stock Awards, Unrestricted Stock Awards, Restricted Stock Units, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of Shares to be covered by any Award and, subject to the provisions of the Plan, the price, exercise price, conversion ratio or other price relating thereto;

(iv) to determine and, subject to Section 12, to modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the form of Award Agreements;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award;

(vi) to impose any limitations on Awards, including limitations on transfers, repurchase provisions and the like, and to exercise repurchase rights or obligations;

(vii) subject to Section 5(a)(ii) and any restrictions imposed by Section 409A, to extend at any time the period in which Stock Options may be exercised; and

(viii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including Award Agreements); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Committee shall be binding on all persons, including the Company and all Holders.

(c) Award Agreement. Awards under the Plan shall be evidenced by Award Agreements that set forth the terms, conditions and limitations for each Award.

(d) Indemnification. Neither the Board nor the Committee, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Committee (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's governing documents, including its certificate of incorporation or bylaws, or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(e) Foreign Award Recipients.¹ Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and any Affiliate operate or have employees or other individuals eligible for Awards, the Committee, in its sole discretion, shall have the power and authority to: (i) determine which Affiliates, if any, shall be covered by the Plan; (ii) determine which individuals, if any, outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Committee determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to the Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitation contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Committee determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS AND OTHER TRANSACTIONS; SUBSTITUTION

(a) Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 624,999 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 6,249,990 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.

(b) Changes in Stock. Subject to Section 3(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding Shares are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional Shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such Shares or other securities, in each case, without the receipt of consideration by the Company, or, if, as a result of any merger or consolidation, or sale of all or substantially all of the assets of the Company, the outstanding Shares are converted into or exchanged for other securities of the Company or any successor entity (or a parent or subsidiary thereof), the Committee shall make an appropriate and proportionate adjustment in (i) the maximum number of Shares reserved for issuance under the Plan, (ii) the number and kind of Shares or other securities subject to any then outstanding Awards under the Plan, (iii) the repurchase price, if any, per Share subject to each outstanding Award, and (iv) the exercise price for each Share subject to any then outstanding Stock Options under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Stock

¹ The Company is advised to consult with foreign counsel before granting awards to foreign recipients.

Options) as to which such Stock Options remain exercisable. The Committee shall in any event make such adjustments as may be required by Section 25102(o) of the California Corporation Code and the rules and regulations promulgated thereunder. The adjustment by the Committee shall be final, binding and conclusive. No fractional Shares shall be issued under the Plan resulting from any such adjustment, but the Committee in its discretion may make a cash payment in lieu of fractional shares.

(c) Sale Events.

(i) Options.

(A) In the case of and subject to the consummation of a Sale Event, the Plan and all outstanding Options issued hereunder shall terminate upon the effective time of any such Sale Event unless assumed or continued by the successor entity, or new stock options or other awards of the successor entity or parent thereof are substituted therefor, with an equitable or proportionate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree (after taking into account any acceleration hereunder and/or pursuant to the terms of any Award Agreement).

(B) In the event of the termination of the Plan and all outstanding Options issued hereunder pursuant to Section 3(c), each Holder of Options shall be permitted, within a period of time prior to the consummation of the Sale Event as specified by the Committee, to exercise all such Options which are then exercisable or will become exercisable as of the effective time of the Sale Event; *provided, however*, that the exercise of Options not exercisable prior to the Sale Event shall be subject to the consummation of the Sale Event.

(C) Notwithstanding anything to the contrary in Section 3(c)(i)(A), in the event of a Sale Event, the Company shall have the right, but not the obligation, to make or provide for a cash payment to the Holders of Options, without any consent of the Holders, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the value as determined by the Committee of the consideration payable per share of Stock pursuant to the Sale Event (the "Sale Price") times the number of Shares subject to outstanding Options being cancelled (to the extent then vested and exercisable, including by reason of acceleration in connection with such Sale Event, at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding vested and exercisable Options.

(ii) Restricted Stock and Restricted Stock Unit Awards.

(A) In the case of and subject to the consummation of a Sale Event, all unvested Restricted Stock and unvested Restricted Stock Unit Awards (other than those becoming vested as a result of the Sale Event) issued hereunder shall be forfeited immediately prior to the effective time of any such Sale Event unless assumed or continued by the successor entity, or awards of the successor entity or parent thereof are substituted therefor, with an equitable or proportionate adjustment as to the number and kind of shares subject to such awards as such parties shall agree (after taking into account any acceleration hereunder and/or pursuant to the terms of any Award Agreement).

(B) In the event of the forfeiture of Restricted Stock pursuant to Section 3(c)(ii)(A), such Restricted Stock shall be repurchased from the Holder thereof at a price per share equal to the original per share purchase price paid by the Holder (subject to adjustment as provided in Section 3(b)) for such Shares.

(C) Notwithstanding anything to the contrary in Section 3(c)(ii)(A), in the event of a Sale Event, the Company shall have the right, but not the obligation, to make or provide for a cash payment to the Holders of Restricted Stock or Restricted Stock Unit Awards, without consent of the Holders, in exchange for the cancellation thereof, in an amount equal to the Sale Price times the number of Shares subject to such Awards, to be paid at the time of such Sale Event or upon the later vesting of such Awards.

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such full or part-time officers and other employees, directors, Consultants and key persons of the Company and any Affiliate who is selected from time to time by the Committee in its sole discretion; provided, however, that Awards shall be granted only to those individuals described in Rule 701(c) of the Securities Act; provided further that Awards may not be granted to employees, Directors or Consultants who are providing services only to any “parent” of the Company, as such term is defined in Rule 405 of the Act, unless (i) the stock underlying the Awards is treated as “service recipient stock” under Section 409A or (ii) the Company has determined that such Awards are exempt from or otherwise comply with Section 409A.

SECTION 5. STOCK OPTIONS

Upon the grant of a Stock Option, the Company and the grantee shall enter into an Award Agreement. The terms and conditions of each such Award Agreement shall be determined by the Committee, and such terms and conditions may differ among individual Awards and grantees.

Stock Options granted under the Plan may be either Incentive Stock Options or Non-Qualified Stock Options. Incentive Stock Options may be granted only to employees of the Company or any Subsidiary that is a “subsidiary corporation” within the meaning of Section 424(f) of the Code. To the extent that any Option does not qualify as an Incentive Stock Option, it shall be deemed a Non-Qualified Stock Option.

(a) Terms of Stock Options. The Committee in its discretion may grant Stock Options to those individuals who meet the eligibility requirements of Section 4. Stock Options shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Committee shall deem desirable.

(i) Exercise Price. The exercise price per share for the Shares covered by a Stock Option shall be determined by the Committee at the time of grant but shall not be less than 100 percent of the Fair Market Value on the Grant Date. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the exercise price per share for the Shares covered by such Incentive Stock Option shall not be less than 110 percent of the Fair Market Value on the Grant Date.

(ii) Option Term. The term of each Stock Option shall be fixed by the Committee, but no Stock Option shall be exercisable more than ten years from the Grant Date. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the term of such Stock Option shall be no more than five years from the Grant Date.

(iii) Exercisability; Rights of a Stockholder. Stock Options shall become exercisable and/or vested at such time or times, whether or not in installments, as shall be determined by the Committee at or after the Grant Date. The Award Agreement may permit a grantee to exercise all or a portion of a Stock Option immediately at grant; provided that the Shares issued upon such exercise shall be subject to restrictions and a vesting schedule identical to the vesting schedule of the related Stock Option, such Shares shall be deemed to be Restricted Stock for purposes of the Plan, and the optionee may be required to enter into an additional or new Award Agreement as a condition to exercise of such Stock Option. An optionee shall have the rights of a stockholder only as to Shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options. An optionee shall not be deemed to have acquired any Shares unless and until a Stock Option shall have been exercised pursuant to the terms of the Award Agreement and this Plan and the optionee's name has been entered on the books of the Company as a stockholder.

(iv) Method of Exercise. Stock Options may be exercised by an optionee in whole or in part, by the optionee giving written or electronic notice of exercise to the Company, specifying the number of Shares to be purchased. Payment of the purchase price may be made by one or more of the following methods (or any combination thereof) to the extent provided in the Award Agreement:

(A) In cash, by certified or bank check, by wire transfer of immediately available funds, or other instrument acceptable to the Committee;

(B) If permitted by the Committee, by the optionee delivering to the Company a promissory note, if the Board has expressly authorized the loan of funds to the optionee for the purpose of enabling or assisting the optionee to effect the exercise of his or her Stock Option; provided, that at least so much of the exercise price as represents the par value of the Stock shall be paid in cash if required by state law;

(C) If permitted by the Committee and the Initial Public Offering has occurred (or the Stock otherwise becomes publicly-traded), through the delivery (or attestation to the ownership) of Shares that have been purchased by the optionee on the open market or that are beneficially owned by the optionee and are not then subject to restrictions under any Company plan. To the extent required to avoid variable accounting treatment under ASC 718 or other applicable accounting rules, such surrendered Shares if originally purchased from the Company shall have been owned by the optionee for at least six months. Such surrendered Shares shall be valued at Fair Market Value on the exercise date;

(D) If permitted by the Committee and the Initial Public Offering has occurred (or the Stock otherwise becomes publicly-traded), by the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the

Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Committee shall prescribe as a condition of such payment procedure; or

(E) If permitted by the Committee, and only with respect to Stock Options that are not Incentive Stock Options, by a “net exercise” arrangement pursuant to which the Company will reduce the number of Shares issuable upon exercise by the largest whole number of Shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. No certificates for Shares so purchased will be issued to the optionee or, with respect to uncertificated Stock, no transfer to the optionee on the records of the Company will take place, until the Company has completed all steps it has deemed necessary to satisfy legal requirements relating to the issuance and sale of the Shares, which steps may include, without limitation, (i) receipt of a representation from the optionee at the time of exercise of the Option that the optionee is purchasing the Shares for the optionee’s own account and not with a view to any sale or distribution of the Shares or other representations relating to compliance with applicable law governing the issuance of securities, (ii) the legending of the certificate (or notation on any book entry) representing the Shares to evidence the foregoing restrictions, and (iii) obtaining from optionee payment or provision for all withholding taxes due as a result of the exercise of the Option. The delivery of certificates representing the shares of Stock (or the transfer to the optionee on the records of the Company with respect to uncertificated Stock) to be purchased pursuant to the exercise of a Stock Option will be contingent upon (A) receipt from the optionee (or a purchaser acting in his or her stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such Shares and the fulfillment of any other requirements contained in the Award Agreement or applicable provisions of laws and (B) if required by the Company, the optionee shall have entered into any stockholders agreements or other agreements with the Company and/or certain other of the Company’s stockholders relating to the Stock. In the event an optionee chooses to pay the purchase price by previously-owned Shares through the attestation method, the number of Shares transferred to the optionee upon the exercise of the Stock Option shall be net of the number of Shares attested to.

(b) Annual Limit on Incentive Stock Options. To the extent required for “incentive stock option” treatment under Section 422 of the Code, the aggregate Fair Market Value (determined as of the Grant Date) of the Shares with respect to which Incentive Stock Options granted under the Plan and any other plan of the Company or its parent and any Subsidiary that become exercisable for the first time by an optionee during any calendar year shall not exceed \$100,000 or such other limit as may be in effect from time to time under Section 422 of the Code. To the extent that any Stock Option exceeds this limit, it shall constitute a Non-Qualified Stock Option.

(c) Termination. Any portion of a Stock Option that is not vested and exercisable on the date of termination of an optionee’s Service Relationship shall immediately expire and be null and void. Once any portion of the Stock Option becomes vested and exercisable, the optionee’s right to exercise such portion of the Stock Option (or the optionee’s representatives and legatees as applicable) in the event of a termination of the optionee’s Service Relationship shall continue until the earliest of: (i) the date which is: (A) 12 months following the date on which the optionee’s

Service Relationship terminates due to death or Disability (or such longer period of time as determined by the Committee and set forth in the applicable Award Agreement), or (B) three months following the date on which the optionee's Service Relationship terminates if the termination is due to any reason other than death or Disability (or such longer period of time as determined by the Committee and set forth in the applicable Award Agreement), or (ii) the Expiration Date set forth in the Award Agreement; provided that notwithstanding the foregoing, an Award Agreement may provide that if the optionee's Service Relationship is terminated for Cause, the Stock Option shall terminate immediately and be null and void upon the date of the optionee's termination and shall not thereafter be exercisable.

SECTION 6. RESTRICTED STOCK AWARDS

(a) Nature of Restricted Stock Awards. The Committee may, in its sole discretion, grant (or sell at par value or such other purchase price determined by the Committee) to an eligible individual under Section 4 hereof a Restricted Stock Award under the Plan. The Committee shall determine the restrictions and conditions applicable to each Restricted Stock Award at the time of grant. Conditions may be based on continuing employment (or other Service Relationship), achievement of pre-established performance goals and objectives and/or such other criteria as the Committee may determine. Upon the grant of a Restricted Stock Award, the Company and the grantee shall enter into an Award Agreement. The terms and conditions of each such Award Agreement shall be determined by the Committee, and such terms and conditions may differ among individual Awards and grantees.

(b) Rights as a Stockholder. Upon the grant of the Restricted Stock Award and payment of any applicable purchase price, a grantee of Restricted Stock shall be considered the record owner of and shall be entitled to vote the Restricted Stock if, and to the extent, such Shares are entitled to voting rights, subject to such conditions contained in the Award Agreement. The grantee shall be entitled to receive all dividends and any other distributions declared on the Shares; provided, however, that the Company is under no duty to declare any such dividends or to make any such distribution. Unless the Committee shall otherwise determine, certificates evidencing the Restricted Stock shall remain in the possession of the Company until such Restricted Stock is vested as provided in subsection (d) below of this Section, and the grantee shall be required, as a condition of the grant, to deliver to the Company a stock power endorsed in blank and such other instruments of transfer as the Committee may prescribe.

(c) Restrictions. Restricted Stock may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Award Agreement. Except as may otherwise be provided by the Committee either in the Award Agreement or, subject to Section 12 below, in writing after the Award Agreement is issued, if a grantee's Service Relationship with the Company and any Affiliate terminates, the Company or its assigns shall have the right, as may be specified in the relevant instrument, to repurchase some or all of the Shares subject to the Award at such purchase price as is set forth in the Award Agreement.

(d) Vesting of Restricted Stock. The Committee at the time of grant shall specify in the Award Agreement the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the substantial risk of forfeiture imposed shall lapse and the Restricted Stock shall become vested, subject to such further rights of the Company or its assigns as may be specified in the Award Agreement.

SECTION 7. UNRESTRICTED STOCK AWARDS

The Committee may, in its sole discretion, grant (or sell at par value or such other purchase price determined by the Committee) to an eligible person under Section 4 hereof an Unrestricted Stock Award under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 8. RESTRICTED STOCK UNITS

(a) Nature of Restricted Stock Units. The Committee may, in its sole discretion, grant to an eligible person under Section 4 hereof Restricted Stock Units under the Plan. The Committee shall determine the restrictions and conditions applicable to each Restricted Stock Unit at the time of grant. Vesting conditions may be based on continuing employment (or other Service Relationship), achievement of pre-established performance goals and objectives and/or other such criteria as the Committee may determine. Upon the grant of Restricted Stock Units, the grantee and the Company shall enter into an Award Agreement. The terms and conditions of each such Award Agreement shall be determined by the Committee and may differ among individual Awards and grantees. On or promptly following the vesting date or dates applicable to any Restricted Stock Unit, but in no event later than March 15 of the year following the year in which such vesting occurs, such Restricted Stock Unit(s) shall be settled in the form of cash or shares of Stock, as specified in the Award Agreement. Restricted Stock Units may not be sold, assigned, transferred, pledged, or otherwise encumbered or disposed of.

(b) Rights as a Stockholder. A grantee shall have the rights of a stockholder only as to Shares, if any, acquired upon settlement of Restricted Stock Units. A grantee shall not be deemed to have acquired any such Shares unless and until the Restricted Stock Units shall have been settled in Shares pursuant to the terms of the Plan and the Award Agreement, the Company shall have issued and delivered a certificate representing the Shares to the grantee (or transferred on the records of the Company with respect to uncertificated stock), and the grantee's name has been entered in the books of the Company as a stockholder.

(c) Termination. Except as may otherwise be provided by the Committee either in the Award Agreement or in writing after the Award Agreement is issued, a grantee's right in all Restricted Stock Units that have not vested shall automatically terminate upon the grantee's cessation of Service Relationship with the Company and any Affiliate for any reason.

SECTION 9. TRANSFER RESTRICTIONS; COMPANY RIGHT OF FIRST REFUSAL; COMPANY REPURCHASE RIGHTS

(a) Restrictions on Transfer.

(i) Non-Transferability of Stock Options. Stock Options and, prior to exercise, the Shares issuable upon exercise of such Stock Option, shall not be transferable by the optionee otherwise than by will, or by the laws of descent and distribution, and all Stock Options shall be exercisable, during the optionee's lifetime, only by the optionee, or by the optionee's legal

representative or guardian in the event of the optionee's incapacity. Notwithstanding the foregoing, the Committee, in its sole discretion, may provide in the Award Agreement regarding a given Stock Option that the optionee may transfer by gift, without consideration for the transfer, his or her Non-Qualified Stock Options to his or her family members (as defined in Rule 701 of the Securities Act), to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners (to the extent such trusts or partnerships are considered "family members" for purposes of Rule 701 of the Securities Act), provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award Agreement, including the execution of a stock power upon the issuance of Shares. Stock Options, and the Shares issuable upon exercise of such Stock Options, shall be restricted as to any pledge, hypothecation, or other transfer, including any short position, any "put equivalent position" (as defined in the Exchange Act) or any "call equivalent position" (as defined in the Exchange Act) prior to exercise.

(ii) Shares. No Shares shall be sold, assigned, transferred, pledged, hypothecated, given away or in any other manner disposed of or encumbered, whether voluntarily or by operation of law, unless (i) the transfer is in compliance with the terms of the applicable Award Agreement, all applicable securities laws (including, without limitation, the Securities Act), and with the terms and conditions of this Section 9, (ii) the transfer does not cause the Company to become subject to the reporting requirements of the Exchange Act, and (iii) the transferee consents in writing to be bound by the provisions of the Plan and the Award Agreement, including this Section 9. In connection with any proposed transfer, the Committee may require the transferor to provide at the transferor's own expense an opinion of counsel to the transferor, satisfactory to the Committee, that such transfer is in compliance with all foreign, federal and state securities laws (including, without limitation, the Securities Act). Any attempted transfer of Shares not in accordance with the terms and conditions of this Section 9 shall be null and void, and the Company shall not reflect on its records any change in record ownership of any Shares as a result of any such transfer, shall otherwise refuse to recognize any such transfer and shall not in any way give effect to any such transfer of Shares. The Company shall be entitled to seek protective orders, injunctive relief and other remedies available at law or in equity including, without limitation, seeking specific performance or the rescission of any transfer not made in strict compliance with the provisions of this Section 9. Subject to the foregoing general provisions, and unless otherwise provided in the applicable Award Agreement, Shares may be transferred pursuant to the following specific terms and conditions (provided that with respect to any transfer of Restricted Stock, all vesting and forfeiture provisions shall continue to apply with respect to the original recipient):

(A) Transfers to Permitted Transferees. The Holder may transfer any or all of the Shares to one or more Permitted Transferees; *provided, however*, that following such transfer, such Shares shall continue to be subject to the terms of this Plan (including this Section 9) and such Permitted Transferee(s) shall, as a condition to any such transfer, deliver a written acknowledgment to that effect to the Company and shall deliver a stock power to the Company with respect to the Shares. Notwithstanding the foregoing, the Holder may not transfer any of the Shares to a Person whom the Company reasonably determines is a direct competitor or a potential competitor of the Company or any of its Subsidiaries.

(B) Transfers Upon Death. Upon the death of the Holder, any Shares then held by the Holder at the time of such death and any Shares acquired after the Holder's death by the Holder's legal representative shall be subject to the provisions of this Plan, and the Holder's estate, executors, administrators, personal representatives, heirs, legatees and distributees shall be obligated to convey such Shares to the Company or its assigns under the terms contemplated by the Plan and the Award Agreement.

(b) Right of First Refusal. In the event that a Holder desires at any time to sell or otherwise transfer all or any part of his or her Shares (other than shares of Restricted Stock which by their terms are not transferrable), the Holder first shall give written notice to the Company of the Holder's intention to make such transfer. Such notice shall state the number of Shares that the Holder proposes to sell (the "Offered Shares"), the price and the terms at which the proposed sale is to be made and the name and address of the proposed transferee. At any time within 30 days after the receipt of such notice by the Company, the Company or its assigns may elect to purchase all or any portion of the Offered Shares at the price and on the terms offered by the proposed transferee and specified in the notice. The Company or its assigns shall exercise this right by mailing or delivering written notice to the Holder within the foregoing 30-day period. If the Company or its assigns elect to exercise its purchase rights under this Section 9(b), the closing for such purchase shall, in any event, take place within 45 days after the receipt by the Company of the initial notice from the Holder. In the event that the Company or its assigns do not elect to exercise such purchase right, or in the event that the Company or its assigns do not pay the full purchase price within such 45-day period, the Holder shall be required to pay a transaction processing fee of \$10,000 to the Company (unless waived by the Committee) and then may, within 60 days thereafter, sell the Offered Shares to the proposed transferee and at the same price and on the same terms as specified in the Holder's notice. Any Shares not sold to the proposed transferee shall remain subject to the Plan. If the Holder is a party to any stockholders agreements or other agreements with the Company and/or certain other of the Company's stockholders relating to the Shares, (i) the transferring Holder shall comply with the requirements of such stockholders agreements or other agreements relating to any proposed transfer of the Offered Shares, and (ii) any proposed transferee that purchases Offered Shares shall enter into such stockholders agreements or other agreements with the Company and/or certain of the Company's stockholders relating to the Offered Shares on the same terms and in the same capacity as the transferring Holder.

(c) Company's Right of Repurchase.

(i) Right of Repurchase for Unvested Shares Issued Upon the Exercise of an Option. Upon a Termination Event, the Company or its assigns shall have the right and option to repurchase from a Holder of Shares acquired upon exercise of a Stock Option which are still subject to a risk of forfeiture as of the Termination Event. Such repurchase rights may be exercised by the Company within the later of (A) six months following the date of such Termination Event or (B) seven months after the acquisition of Shares upon exercise of a Stock Option. The repurchase price shall be equal to the lower of the original per share price paid by the Holder, subject to adjustment as provided in Section 3(b) of the Plan, or the current Fair Market Value of such Shares as of the date the Company elects to exercise its repurchase rights.

(ii) Right of Repurchase With Respect to Restricted Stock. Upon a Termination Event, the Company or its assigns shall have the right and option to repurchase from a Holder of Shares received pursuant to a Restricted Stock Award any Shares that are still subject to a risk of forfeiture as of the Termination Event. Such repurchase right may be exercised by the Company within six months following the date of such Termination Event. The repurchase price shall be the lower of the original per share purchase price paid by the Holder, subject to adjustment as provided in Section 3(b) of the Plan, or the current Fair Market Value of such Shares as of the date the Company elects to exercise its repurchase rights.

(iii) Procedure. Any repurchase right of the Company shall be exercised by the Company or its assigns by giving the Holder written notice on or before the last day of the repurchase period of its intention to exercise such repurchase right. Upon such notification, the Holder shall promptly surrender to the Company, free and clear of any liens or encumbrances, any certificates representing the Shares being purchased, together with a duly executed stock power for the transfer of such Shares to the Company or the Company's assignee or assignees. Upon the Company's or its assignee's receipt of the certificates from the Holder, the Company or its assignee or assignees shall deliver to him, her or them a check for the applicable repurchase price; *provided, however*, that the Company may pay the repurchase price by offsetting and canceling any indebtedness then owed by the Holder to the Company.

(d) Drag Along Right. In the event the holders of a majority of the Company's equity securities then outstanding (the "Majority Shareholders") determine to enter into a Sale Event in a bona fide negotiated transaction (a "Sale"), with any non-Affiliate of the Company or any majority shareholder (in each case, the "Buyer"), a Holder of Shares, including any Permitted Transferee, shall be obligated to and shall upon the written request of the Majority Shareholders: (a) sell, transfer and deliver, or cause to be sold, transferred and delivered, to the Buyer, his or her Shares (including for this purpose all of such Holder's Shares that presently or as a result of any such transaction may be acquired upon the exercise of an Option (following the payment of the exercise price therefor)) on substantially the same terms applicable to the Majority Shareholders (with appropriate adjustments to reflect the conversion of convertible securities, the redemption of redeemable securities and the exercise of exercisable securities as well as the relative preferences and priorities of preferred stock); and (b) execute and deliver such instruments of conveyance and transfer and take such other action, including voting such Shares in favor of any Sale proposed by the Majority Shareholders and executing any purchase agreements, merger agreements, indemnity agreements, escrow agreements or related documents as the Majority Shareholders or the Buyer may reasonably require in order to carry out the terms and provisions of this Section 9(d).

(e) Escrow Arrangement.

(i) Escrow. In order to carry out the provisions of this Section 9 of this Plan more effectively, the Company shall hold any Shares issued pursuant to Awards granted under the Plan in escrow together with separate stock powers executed by the Holder in blank for transfer. The Company shall not dispose of the Shares except as otherwise provided in this Plan. In the event of any repurchase by the Company (or any of its assigns), the Company is hereby authorized by the Holder, as the Holder's attorney-in-fact, to date and complete the stock powers necessary for the transfer of the Shares being purchased and to transfer such Shares in accordance with the terms hereof. At such time as any Shares are no longer subject to the Company's repurchase and first refusal rights, the Company shall, at the written request of the Holder, deliver to the Holder a certificate representing such Shares with the balance of the Shares to be held in escrow pursuant to this Section.

(ii) Remedy. Without limitation of any other provision of this Plan or other rights, in the event that a Holder or any other Person is required to sell a Holder's Shares pursuant to the provisions of Sections 9(b) or (c) hereof and in the further event that he or she refuses or for any reason fails to deliver to the Company or its designated purchaser of such Shares the certificate or certificates evidencing such Shares together with a related stock power, the Company or such designated purchaser may deposit the applicable purchase price for such Shares with a bank designated by the Company, or with the Company's independent public accounting firm, as agent or trustee, or in escrow, for such Holder or other Person, to be held by such bank or accounting firm for the benefit of and for delivery to him, her, them or it, and/or, in its discretion, pay such purchase price by offsetting any indebtedness then owed by such Holder as provided above. Upon any such deposit and/or offset by the Company or its designated purchaser of such amount and upon notice to the Person who was required to sell the Shares to be sold pursuant to the provisions of Sections 9(b) or (c), such Shares shall at such time be deemed to have been sold, assigned, transferred and conveyed to such purchaser, such Holder shall have no further rights thereto (other than the right to withdraw the payment thereof held in escrow, if applicable), and the Company shall record such transfer in its stock transfer book or in any appropriate manner.

(f) Lockup Provision. If requested by the Company, a Holder shall not sell or otherwise transfer or dispose of any Shares (including, without limitation, pursuant to Rule 144 under the Securities Act) held by him or her for such period following the effective date of a public offering by the Company of Shares as the Company shall specify reasonably and in good faith. If requested by the underwriter engaged by the Company, each Holder shall execute a separate letter confirming his or her agreement to comply with this Section.

(g) Adjustments for Changes in Capital Structure. If, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Common Stock, the outstanding Shares are increased or decreased or are exchanged for a different number or kind of securities of the Company, the restrictions contained in this Section 9 shall apply with equal force to additional and/or substitute securities, if any, received by Holder in exchange for, or by virtue of his or her ownership of, Shares.

(h) Termination. The terms and provisions of Section 9(b) and Section 9(c) (except for the Company's right to repurchase Shares still subject to a risk of forfeiture upon a Termination Event) shall terminate upon the closing of the Company's Initial Public Offering or upon consummation of any Sale Event, in either case as a result of which Shares are registered under Section 12 of the Exchange Act and publicly-traded on any national security exchange.

SECTION 10. TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Shares or other amounts received thereunder first becomes includable in the gross income of the grantee for income tax purposes, pay to the Company, or make arrangements satisfactory to the Committee regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and any Affiliate shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver stock certificates (or evidence of book entry) to any grantee is subject to and conditioned on any such tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. The Company's minimum required tax withholding obligation may be satisfied, in whole or in part, by the Company withholding from Shares to be issued pursuant to an Award a number of Shares having an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the minimum withholding amount due.

SECTION 11. SECTION 409A AWARDS

To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as may be specified by the Committee from time to time. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. The Company makes no representation or warranty and shall have no liability to any grantee under the Plan or any other Person with respect to any penalties or taxes under Section 409A that are, or may be, imposed with respect to any Award.

SECTION 12. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Committee may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding Award without the consent of the holder of the Award. The Committee may exercise its discretion to reduce the exercise price of outstanding Stock Options or effect repricing through cancellation of outstanding Stock Options and by granting such holders new Awards in replacement of the cancelled Stock Options. To the extent determined by the Committee to be required either by the Code to ensure that Incentive Stock Options granted under the Plan are qualified under Section 422 of the Code or otherwise, Plan amendments shall be subject to approval by the Company stockholders entitled to vote at a meeting of stockholders. Nothing in this Section 12 shall limit the Board's or Committee's authority to take any action permitted pursuant to Section 3(c). The Board reserves the right to amend the Plan and/or the terms of any outstanding Stock Options to the extent reasonably necessary to comply with the requirements of the exemption pursuant to paragraph (f)(4) of Rule 12h-1 of the Exchange Act.

SECTION 13. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Committee shall otherwise expressly so determine in connection with any Award.

SECTION 14. GENERAL PROVISIONS

(a) No Distribution; Compliance with Legal Requirements. The Committee may require each person acquiring Shares pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the Shares without a view to distribution thereof. No Shares shall be issued pursuant to an Award until all applicable securities law and other legal and stock exchange or similar requirements have been satisfied. The Committee may require the placing of such stop-orders and restrictive legends on certificates for Stock and Awards as it deems appropriate.

(b) Delivery of Stock Certificates. Stock certificates to grantees under the Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company; provided that stock certificates to be held in escrow pursuant to Section 9 of the Plan shall be deemed delivered when the Company shall have recorded the issuance in its records. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records).

(c) No Employment Rights. The adoption of the Plan and the grant of Awards do not confer upon any Person any right to continued employment or Service Relationship with the Company or any Affiliate.

(d) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policy-related restrictions, terms and conditions as may be established by the Committee, or in accordance with policies set by the Committee, from time to time.

(e) Designation of Beneficiary. Each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award on or after the grantee's death or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Committee and shall not be effective until received by the Committee. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

(f) Legend. Any certificate(s) representing the Shares shall carry substantially the following legend (and with respect to uncertificated Stock, the book entries evidencing such shares shall contain the following notation):

The transferability of this certificate and the shares of stock represented hereby are subject to the restrictions, terms and conditions (including repurchase and restrictions against transfers) contained in the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan and any agreements entered into thereunder by and between the company and the holder of this certificate (a copy of which is available at the offices of the company for examination).

(g) Information to Holders of Options. In the event the Company is relying on the exemption from the registration requirements of Section 12(g) of the Exchange Act contained in paragraph (f)(1) of Rule 12h-1 of the Exchange Act, the Company shall provide the information described in Rule 701(e)(3), (4) and (5) of the Securities Act to all holders of Options in accordance with the requirements thereunder. The foregoing notwithstanding, the Company shall not be required to provide such information unless the optionholder has agreed in writing, on a form prescribed by the Company, to keep such information confidential.

SECTION 15. EFFECTIVE DATE OF PLAN

The Plan shall become effective upon adoption by the Board and shall be approved by stockholders in accordance with applicable state law and the Company's articles of incorporation and bylaws within 12 months thereafter. If the stockholders fail to approve the Plan within 12 months after its adoption by the Board of Directors, then any Awards granted or sold under the Plan shall be rescinded and no additional grants or sales shall thereafter be made under the Plan. Subject to such approval by stockholders and to the requirement that no Shares may be issued hereunder prior to such approval, Stock Options and other Awards may be granted hereunder on and after adoption of the Plan by the Board. No grants of Stock Options and other Awards may be made hereunder after the tenth anniversary of the date the Plan is adopted by the Board or the date the Plan is approved by the Company's stockholders, whichever is earlier.

SECTION 16. GOVERNING LAW

This Plan, all Awards and any controversy arising out of or relating to this Plan and all Awards shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts.

DATE ADOPTED BY THE BOARD OF DIRECTORS:

June 14, 2019

DATE APPROVED BY THE STOCKHOLDERS:

July 17, 2019

BICARA THERAPEUTICS INC.
AMENDMENT NO. 1 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the “Plan”) is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

“Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 16,000,000 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 160,000,000 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

ADOPTED BY BOARD OF DIRECTORS:

September 15, 2020

ADOPTED BY STOCKHOLDERS:

September 15, 2020

BICARA THERAPEUTICS INC.
AMENDMENT NO. 2 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the "Plan") is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

"Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 24,000,000 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 240,000,000 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company."

ADOPTED BY BOARD OF DIRECTORS:

December 23, 2020

ADOPTED BY STOCKHOLDERS:

December 23, 2020

BICARA THERAPEUTICS INC.
AMENDMENT NO. 3 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the “Plan”) is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

“Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 13,472,000 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 134,720,000 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

ADOPTED BY BOARD OF DIRECTORS:

April 21, 2022

ADOPTED BY STOCKHOLDERS:

April 26, 2022

BICARA THERAPEUTICS INC.
AMENDMENT NO. 4 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the “Plan”) is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

“Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 19,524,059 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 195,240,590 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

ADOPTED BY BOARD OF DIRECTORS: March 2, 2023

ADOPTED BY STOCKHOLDERS: March 2, 2023

BICARA THERAPEUTICS INC.
AMENDMENT NO. 5 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the “Plan”) is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

“Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 33,256,845 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 332,568,450 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

ADOPTED BY BOARD OF DIRECTORS: August 8, 2023

ADOPTED BY STOCKHOLDERS: August 24, 2023

BICARA THERAPEUTICS INC.
AMENDMENT NO. 6 TO THE
2019 STOCK OPTION AND GRANT PLAN

The Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the “Plan”) is hereby amended by the Board of Directors and stockholders of Bicara Therapeutics Inc., a Delaware corporation, as follows:

The first sentence of Section 3(a) of the Plan is hereby amended by deleting it and replacing it with the following:

“Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 54,362,703 Shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the Shares underlying any Awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) and Shares that are withheld upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding shall be added back to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award, and no more than 543,627,030 Shares may be issued pursuant to Incentive Stock Options. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

ADOPTED BY BOARD OF DIRECTORS: December 6, 2023

ADOPTED BY STOCKHOLDERS: December 6, 2023

**INCENTIVE STOCK OPTION GRANT NOTICE
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

Pursuant to the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the "Plan"), Bicara Therapeutics Inc., a Delaware corporation (together with any successor, the "Company"), has granted to the individual named below, an option (the "Stock Option") to purchase on or prior to the Expiration Date, or such earlier date as is specified herein, all or any part of the number of shares of Common Stock, par value \$0.0001 per share ("Common Stock"), of the Company indicated below (the "Shares"), at the Option Exercise Price per share, subject to the terms and conditions set forth in this Incentive Stock Option Grant Notice (the "Grant Notice"), the attached Incentive Stock Option Agreement (the "Agreement") and the Plan. This Stock Option is intended to qualify as an "incentive stock option" as defined in Section 422(b) of the Internal Revenue Code of 1986, as amended from time to time (the "Code"). To the extent that any portion of the Stock Option does not so qualify, it shall be deemed a non-qualified stock option.

Name of Optionee: _____ (the "Optionee")
No. of Shares: _____ Shares of Common Stock
Grant Date: _____
Vesting Commencement Date: _____ (the "Vesting Commencement Date")
Expiration Date: _____ (the "Expiration Date")
Option Exercise Price/Share: \$ _____ (the "Option Exercise Price")

Vesting Schedule:

25% of the Shares shall vest on the [first] anniversary of the Vesting Commencement Date; provided that the Grantee remains an employee of the Company or any Affiliate at such time. Thereafter, the remaining 75% of the Shares shall vest in 12 equal quarterly installments following the first anniversary of the Vesting Commencement Date, provided the Grantee remains an employee of the Company or any Affiliate at such time.

Notwithstanding anything in the Agreement to the contrary, in the case of a Sale Event, this Stock Option and the Shares shall be treated as provided in Section 3(c) of the Plan[provided; however INSERT ANY ACCELERATED VESTING PROVISION HERE].

Attachments: Incentive Stock Option Agreement, 2019 Stock Option and Grant Plan

**INCENTIVE STOCK OPTION AGREEMENT
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

All capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Grant Notice and the Plan.

SECTION 17. VESTING, EXERCISABILITY AND TERMINATION.

(a) No portion of this Stock Option may be exercised until such portion shall have vested and become exercisable.

(b) Except as set forth below, and subject to the determination of the Committee in its sole discretion to accelerate the vesting schedule hereunder, this Stock Option shall be vested and exercisable on the respective dates indicated below:

(i) This Stock Option shall initially be unvested and unexercisable.

(ii) This Stock Option shall vest and become exercisable in accordance with the Vesting Schedule set forth in the Grant Notice.

(c) Termination. Except as may otherwise be provided by the Committee, if the Optionee's employment with the Company or any Affiliate is terminated, the period within which to exercise this Stock Option will be subject to earlier termination as set forth below (and if not exercised within such period, shall thereafter terminate subject, in each case, to Section 3(c) of the Plan):

(i) Termination Due to Death or Disability. If the Optionee's employment with the Company or any Affiliate terminates by reason of such Optionee's death or Disability, this Stock Option may be exercised, to the extent exercisable on the date of such termination, by the Optionee, the Optionee's legal representative or legatee for a period of 12 months from the date of death or Disability or until the Expiration Date, if earlier.

(ii) Other Termination. If the Optionee's employment with the Company or any Affiliate terminates for any reason other than death or Disability, and unless otherwise determined by the Committee, this Stock Option may be exercised, to the extent exercisable on the date of termination, for a period of 90 days from the date of termination or until the Expiration Date, if earlier; provided however, if the Optionee's employment is terminated for Cause, this Stock Option shall terminate immediately upon the date of such termination.

For purposes hereof, the Committee's determination of the reason for termination of the Optionee's employment with the Company or any Affiliate shall be conclusive and binding on the Optionee and his or her representatives or legatees. Any portion of this Stock Option that is not vested and exercisable on the date of termination of the Optionee's employment with the Company or any Affiliate shall terminate immediately and be null and void.

(d) It is understood and intended that this Stock Option is intended to qualify as an “incentive stock option” as defined in Section 422 of the Code to the extent permitted under applicable law. Accordingly, the Optionee understands that in order to obtain the benefits of an incentive stock option under Section 422 of the Code, no sale or other disposition may be made of Shares for which incentive stock option treatment is desired within the one-year period beginning on the day after the day of the transfer of such Shares to him or her, nor within the two-year period beginning on the day after Grant Date of this Stock Option and further that this Stock Option must be exercised within three months after termination of employment as an employee (or 12 months in the case of death or disability) to qualify as an incentive stock option. If the Optionee disposes (whether by sale, gift, transfer or otherwise) of any such Shares within either of these periods, he or she will notify the Company within 30 days after such disposition. The Optionee also agrees to provide the Company with any information concerning any such dispositions required by the Company for tax purposes. Further, to the extent this Stock Option and any other incentive stock options of the Optionee having an aggregate Fair Market Value in excess of \$100,000 (determined as of the Grant Date) first become exercisable in any year, such options will not qualify as incentive stock options.

SECTION 18. EXERCISE OF STOCK OPTION.

(a) The Optionee may exercise this Stock Option only in the following manner: Prior to the Expiration Date, the Optionee may deliver a Stock Option exercise notice (an “Exercise Notice”) in the form of Appendix A hereto indicating his or her election to purchase some or all of the Shares with respect to which this Stock Option is then exercisable. Such notice shall specify the number of Shares to be purchased. Payment of the purchase price may be made by one or more of the methods described in Section 5 of the Plan, subject to the limitations contained in such Section of the Plan, including the requirement that the Committee specifically approve in advance certain payment methods.

(b) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date.

SECTION 19. INCORPORATION OF PLAN. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THIS STOCK OPTION SHALL BE SUBJECT TO AND GOVERNED BY ALL THE TERMS AND CONDITIONS OF THE PLAN.

SECTION 20. TRANSFERABILITY OF STOCK OPTION. THIS STOCK OPTION IS PERSONAL TO THE OPTIONEE AND IS NOT TRANSFERABLE BY THE OPTIONEE IN ANY MANNER OTHER THAN BY WILL OR BY THE LAWS OF DESCENT AND DISTRIBUTION. THE STOCK OPTION MAY BE EXERCISED DURING THE OPTIONEE’S LIFETIME ONLY BY THE OPTIONEE (OR BY THE OPTIONEE’S GUARDIAN OR PERSONAL REPRESENTATIVE IN THE EVENT OF THE OPTIONEE’S INCAPACITY). THE OPTIONEE MAY ELECT TO DESIGNATE A BENEFICIARY BY PROVIDING WRITTEN NOTICE OF THE NAME OF SUCH BENEFICIARY TO THE COMPANY, AND MAY REVOKE OR CHANGE SUCH DESIGNATION AT ANY TIME BY FILING WRITTEN NOTICE OF REVOCATION OR CHANGE WITH THE COMPANY; SUCH BENEFICIARY

MAY EXERCISE THE OPTIONEE'S STOCK OPTION IN THE EVENT OF THE OPTIONEE'S DEATH TO THE EXTENT PROVIDED HEREIN. IF THE OPTIONEE DOES NOT DESIGNATE A BENEFICIARY, OR IF THE DESIGNATED BENEFICIARY PREDECEASES THE OPTIONEE, THE LEGAL REPRESENTATIVE OF THE OPTIONEE MAY EXERCISE THIS STOCK OPTION TO THE EXTENT PROVIDED HEREIN IN THE EVENT OF THE OPTIONEE'S DEATH.

SECTION 21. RESTRICTIONS ON TRANSFER OF SHARES. THE SHARES ACQUIRED UPON EXERCISE OF THE STOCK OPTION SHALL BE SUBJECT TO CERTAIN TRANSFER RESTRICTIONS AND OTHER LIMITATIONS INCLUDING, WITHOUT LIMITATION, THE PROVISIONS CONTAINED IN SECTION 9 OF THE PLAN.

SECTION 22. MISCELLANEOUS PROVISIONS.

(a) Equitable Relief. The parties hereto agree and declare that legal remedies may be inadequate to enforce the provisions of this Agreement and that equitable relief, including specific performance and injunctive relief, may be used to enforce the provisions of this Agreement.

(b) Adjustments for Changes in Capital Structure. If, as a result of any reorganization, recapitalization, reincorporation, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Common Stock, the outstanding shares of Common Stock are increased or decreased or are exchanged for a different number or kind of securities of the Company, the restrictions contained in this Agreement shall apply with equal force to additional and/or substitute securities, if any, received by the Optionee in exchange for, or by virtue of his or her ownership of, this Stock Option or Shares acquired pursuant thereto.

(c) Change and Modifications. This Agreement may not be orally changed, modified or terminated, nor shall any oral waiver of any of its terms be effective. This Agreement may be changed, modified or terminated only by an agreement in writing signed by the Company and the Optionee.

(d) Governing Law. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts.

(e) Headings. The headings are intended only for convenience in finding the subject matter and do not constitute part of the text of this Agreement and shall not be considered in the interpretation of this Agreement.

(f) Saving Clause. If any provision(s) of this Agreement shall be determined to be illegal or unenforceable, such determination shall in no manner affect the legality or enforceability of any other provision hereof.

(g) **Notices.** All notices, requests, consents and other communications shall be in writing and be deemed given when delivered personally, by telex or facsimile transmission or when received if mailed by first class registered or certified mail, postage prepaid. Notices to the Company or the Optionee shall be addressed as set forth underneath their signatures below, or to such other address or addresses as may have been furnished by such party in writing to the other.

(h) **Benefit and Binding Effect.** This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their respective successors, assigns, and legal representatives. The Company has the right to assign this Agreement, and such assignee shall become entitled to all the rights of the Company hereunder to the extent of such assignment.

(i) **Counterparts.** For the convenience of the parties and to facilitate execution, this Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same document.

(j) **Integration.** This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 23. DISPUTE RESOLUTION.

(a) Except as provided below, any dispute arising out of or relating to the Plan or this Stock Option, this Agreement, or the breach, termination or validity of the Plan, this Stock Option or this Agreement, shall be finally settled by binding arbitration conducted expeditiously in accordance with the J.A.M.S./Endispute Comprehensive Arbitration Rules and Procedures (the "J.A.M.S. Rules"). The arbitration shall be governed by the United States Arbitration Act, 9 U.S.C. Sections 1-16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The place of arbitration shall be Boston, Massachusetts.

(b) The arbitration shall commence within 60 days of the date on which a written demand for arbitration is filed by any party hereto. In connection with the arbitration proceeding, the arbitrator shall have the power to order the production of documents by each party and any third-party witnesses. In addition, each party may take up to three depositions as of right, and the arbitrator may in his or her discretion allow additional depositions upon good cause shown by the moving party. However, the arbitrator shall not have the power to order the answering of interrogatories or the response to requests for admission. In connection with any arbitration, each party to the arbitration shall provide to the other, no later than seven business days before the date of the arbitration, the identity of all persons that may testify at the arbitration and a copy of all documents that may be introduced at the arbitration or considered or used by a party's witness or expert. The arbitrator's decision and award shall be made and delivered within six months of the selection of the arbitrator. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages, and each party hereby irrevocably waives any claim to such damages.

(c) The Company, the Optionee, each party to the Agreement and any other holder of Shares issued pursuant to this Agreement (each, a "Party") covenants and agrees that such party will participate in the arbitration in good faith. This Section 7 applies equally to requests for temporary, preliminary or permanent injunctive relief, except that in the case of temporary or preliminary injunctive relief any party may proceed in court without prior arbitration for the limited purpose of avoiding immediate and irreparable harm.

(d) Each Party (i) hereby irrevocably submits to the jurisdiction of any United States District Court of competent jurisdiction for the purpose of enforcing the award or decision in any such proceeding, (ii) hereby waives, and agrees not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above named courts, that its property is exempt or immune from attachment or execution (except as protected by applicable law), that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (iii) hereby waives and agrees not to seek any review by any court of any other jurisdiction which may be called upon to grant an enforcement of the judgment of any such court. Each Party hereby consents to service of process by registered mail at the address to which notices are to be given. Each Party agrees that its, his or her submission to jurisdiction and its, his or her consent to service of process by mail is made for the express benefit of each other Party. Final judgment against any Party in any such action, suit or proceeding may be enforced in other jurisdictions by suit, action or proceeding on the judgment, or in any other manner provided by or pursuant to the laws of such other jurisdiction.

SECTION 24. WAIVER OF STATUTORY INFORMATION RIGHTS. THE OPTIONEE UNDERSTANDS AND AGREES THAT, BUT FOR THE WAIVER MADE HEREIN, THE OPTIONEE WOULD BE ENTITLED, UPON WRITTEN DEMAND UNDER OATH STATING THE PURPOSE THEREOF, TO INSPECT FOR ANY PROPER PURPOSE, AND TO MAKE COPIES AND EXTRACTS FROM, THE COMPANY'S STOCK LEDGER, A LIST OF ITS STOCKHOLDERS, AND ITS OTHER BOOKS AND RECORDS, AND THE BOOKS AND RECORDS OF SUBSIDIARIES OF THE COMPANY, IF ANY, UNDER THE CIRCUMSTANCES AND IN THE MANNER PROVIDED IN SECTION 220 OF THE GENERAL CORPORATION LAW OF DELAWARE (ANY AND ALL SUCH RIGHTS, AND ANY AND ALL SUCH OTHER RIGHTS OF THE OPTIONEE AS MAY BE PROVIDED FOR IN SECTION 220, THE "INSPECTION RIGHTS"). IN LIGHT OF THE FOREGOING, UNTIL THE FIRST SALE OF STOCK OF THE COMPANY TO THE GENERAL PUBLIC PURSUANT TO A REGISTRATION STATEMENT FILED WITH AND DECLARED EFFECTIVE BY THE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES ACT, THE OPTIONEE HEREBY UNCONDITIONALLY AND IRREVOCABLY WAIVES THE INSPECTION RIGHTS, WHETHER SUCH INSPECTION RIGHTS WOULD BE EXERCISED OR PURSUED DIRECTLY OR INDIRECTLY PURSUANT TO SECTION 220 OR OTHERWISE, AND COVENANTS AND AGREES NEVER TO DIRECTLY OR INDIRECTLY COMMENCE, VOLUNTARILY AID IN ANY WAY, PROSECUTE, ASSIGN, TRANSFER,

OR CAUSE TO BE COMMENCED ANY CLAIM, ACTION, CAUSE OF ACTION, OR OTHER PROCEEDING TO PURSUE OR EXERCISE THE INSPECTION RIGHTS. THE FOREGOING WAIVER SHALL NOT AFFECT ANY RIGHTS OF A DIRECTOR, IN HIS OR HER CAPACITY AS SUCH, UNDER SECTION 220. THE FOREGOING WAIVER SHALL NOT APPLY TO ANY CONTRACTUAL INSPECTION RIGHTS OF THE OPTIONEE UNDER ANY OTHER WRITTEN AGREEMENT BETWEEN THE OPTIONEE AND THE COMPANY.

[SIGNATURE PAGE FOLLOWS]

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned as of the date first above written.

BICARA THERAPEUTICS INC.

By: _____

Name:

Title:

Address:

The undersigned hereby acknowledges receiving and reviewing a copy of the Plan, including, without limitation, Section 9 thereof, and understands that this Stock Option is subject to the terms of the Plan and of this Agreement. This Agreement is hereby accepted, and the terms and conditions of the Plan, the Grant Notice and this Agreement, SPECIFICALLY INCLUDING THE ARBITRATION PROVISIONS SET FORTH IN SECTION 7 AND THE WAIVER OF STATUTORY INFORMATION RIGHTS SET FORTH IN SECTION 8 OF THIS AGREEMENT, are hereby agreed to, by the undersigned as of the date first above written.

OPTIONEE:

Name:

Address:

[SPOUSE'S CONSENT²

I acknowledge that I have read the
foregoing Incentive Stock Option Agreement
and understand the contents thereof.

_____]

² A spouse's consent is recommended only if the Optionee's state of residence is one of the following community property states: Arizona, California, Idaho, Louisiana, Nevada, New Mexico, Texas, Washington and Wisconsin.

DESIGNATED BENEFICIARY:

Beneficiary's Address:

Appendix A

STOCK OPTION EXERCISE NOTICE

Bicara Therapeutics Inc.

Attention: [_____]

Pursuant to the terms of the grant notice and stock option agreement between the undersigned and Bicara Therapeutics Inc. (the "Company") dated _____ (the "Agreement") under the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan, I, [Insert Name] _____, hereby [Circle One] partially/fully exercise such option by including herein payment in the amount of \$ _____ representing the purchase price for [Fill in number of Shares] _____ Shares. I have chosen the following form(s) of payment:

- 1. Cash
- 2. Certified or bank check payable to Bicara Therapeutics Inc.
- 3. Other (as referenced in the Agreement and described in the Plan (please describe))

_____.

In connection with my exercise of the option as set forth above, I hereby represent and warrant to the Company as follows:

- (i) I am purchasing the Shares for my own account for investment only, and not for resale or with a view to the distribution thereof.
- (ii) I have had such an opportunity as I have deemed adequate to obtain from the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company and have consulted with my own advisers with respect to my investment in the Company.
- (iii) I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
- (iv) I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period of time.
- (v) I understand that the Shares may not be registered under the Securities Act of 1933 (it being understood that the Shares are being issued and sold in reliance on the exemption provided in Rule 701 thereunder) or any applicable state securities or "blue sky" laws and may not be sold or otherwise transferred or disposed of in the absence of an effective registration statement under the Securities Act of 1933 and under any applicable state securities or "blue sky" laws (or exemptions from the registration requirement thereof). I further acknowledge that certificates representing Shares will bear restrictive legends reflecting the foregoing and/or that book entries for uncertificated Shares will include similar restrictive notations.

(vi) I have read and understand the Plan and acknowledge and agree that the Shares are subject to all of the relevant terms of the Plan, including without limitation, the transfer restrictions set forth in Section 9 of the Plan.

(vii) I understand and agree that the Company has a right of first refusal with respect to the Shares pursuant to Section 9(b) of the Plan.

(viii) I understand and agree that the Company has certain repurchase rights with respect to the Shares pursuant to Section 9(c) of the Plan.

(ix) I understand and agree that I may not sell or otherwise transfer or dispose of the Shares for a period of time following the effective date of a public offering by the Company as described in Section 9(f) of the Plan.

(x) I understand and agree to the waiver of statutory information rights as set forth in Section 8 of the Agreement.

Sincerely yours,

Name:

Address:

Date: _____

**NON-QUALIFIED STOCK OPTION GRANT NOTICE
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

Pursuant to the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the "Plan"), Bicara Therapeutics Inc., a Delaware corporation (together with any successor, the "Company"), has granted to the individual named below, an option (the "Stock Option") to purchase on or prior to the Expiration Date, or such earlier date as is specified herein, all or any part of the number of shares of Common Stock, par value \$0.0001 per share ("Common Stock"), of the Company indicated below (the "Shares"), at the Option Exercise Price per share, subject to the terms and conditions set forth in this Non-Qualified Stock Option Grant Notice (the "Grant Notice"), the attached Non-Qualified Stock Option Agreement (the "Agreement") and the Plan. This Stock Option is not intended to qualify as an "incentive stock option" as defined in Section 422(b) of the Internal Revenue Code of 1986, as amended from time to time (the "Code").

Name of Optionee: _____ (the "Optionee")

No. of Shares: _____ Shares of Common Stock

Grant Date: _____

Vesting Commencement Date: _____ (the "Vesting Commencement Date")

Expiration Date: _____ (the "Expiration Date")

Option Exercise Price/Share: \$ _____ (the "Option Exercise Price")

Vesting Schedule: [25] percent of the Shares shall vest and become exercisable on the first anniversary of the Vesting Commencement Date; provided that the Optionee remains an employee³ of the Company or any Affiliate at such time. Thereafter, the remaining [75] percent of the Shares shall vest and become exercisable in [12] equal quarterly installments following the first anniversary of the Vesting Commencement Date, provided the Optionee remains an employee of the Company or any Affiliate on each vesting date. Notwithstanding anything in the Agreement to the contrary, in the case of a Sale Event, this Stock Option and the Shares shall be treated as provided in Section 3(c) of the Plan[provided; however INSERT ANY ACCELERATED VESTING PROVISION HERE].

Attachments: Non-Qualified Stock Option Agreement, 2019 Stock Option and Grant Plan

³ Update references to employment to the extent individual provides services in another capacity.

**NON-QUALIFIED STOCK OPTION AGREEMENT
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

All capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Grant Notice and the Plan.

SECTION 25. VESTING, EXERCISABILITY AND TERMINATION.

(a) No portion of this Stock Option may be exercised until such portion shall have vested and become exercisable.

(b) Except as set forth below, and subject to the determination of the Committee in its sole discretion to accelerate the vesting schedule hereunder, this Stock Option shall be vested and exercisable on the respective dates indicated below:

(i) This Stock Option shall initially be unvested and unexercisable.

(ii) This Stock Option shall vest and become exercisable in accordance with the Vesting Schedule set forth in the Grant Notice.

(c) Termination. Except as may otherwise be provided by the Committee, if the Optionee's employment with the Company or any Affiliate is terminated, the period within which to exercise this Stock Option will be subject to earlier termination as set forth below (and if not exercised within such period, shall thereafter terminate subject, in each case, to Section 3(c) of the Plan):

(i) Termination Due to Death or Disability. If the Optionee's employment with the Company or any Affiliate terminates by reason of such Optionee's death or Disability, this Stock Option may be exercised, to the extent exercisable on the date of such termination, by the Optionee, the Optionee's legal representative or legatee for a period of 12 months from the date of death or Disability or until the Expiration Date, if earlier.

(ii) Other Termination. If the Optionee's employment with the Company or any Affiliate terminates for any reason other than death or Disability, and unless otherwise determined by the Committee, this Stock Option may be exercised, to the extent exercisable on the date of termination, for a period of 90 days from the date of termination or until the Expiration Date, if earlier; provided however, if the Optionee's employment is terminated for Cause, this Stock Option shall terminate immediately upon the date of such termination.

For purposes hereof, the Committee's determination of the reason for termination of the Optionee's employment with the Company or any Affiliate shall be conclusive and binding on the Optionee and his or her representatives or legatees and any Permitted Transferee. Any portion of this Stock Option that is not vested and exercisable on the date of termination of the Optionee's employment with the Company or any Affiliate shall terminate immediately and be null and void.

SECTION 26. EXERCISE OF STOCK OPTION.

(a) The Optionee may exercise this Stock Option only in the following manner: Prior to the Expiration Date, the Optionee may deliver a Stock Option exercise notice (an "Exercise Notice") in the form of Appendix A hereto indicating his or her election to purchase some or all of the Shares with respect to which this Stock Option is then exercisable. Such notice shall specify the number of Shares to be purchased. Payment of the purchase price may be made by one or more of the methods described in Section 5 of the Plan, subject to the limitations contained in such Section of the Plan, including the requirement that the Committee specifically approve in advance certain payment methods.

(b) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date.

SECTION 27. INCORPORATION OF PLAN. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THIS STOCK OPTION SHALL BE SUBJECT TO AND GOVERNED BY ALL THE TERMS AND CONDITIONS OF THE PLAN.

SECTION 28. TRANSFERABILITY OF STOCK OPTION. THIS STOCK OPTION IS PERSONAL TO THE OPTIONEE AND IS NOT TRANSFERABLE BY THE OPTIONEE IN ANY MANNER OTHER THAN BY WILL OR BY THE LAWS OF DESCENT AND DISTRIBUTION. THE STOCK OPTION MAY BE EXERCISED DURING THE OPTIONEE'S LIFETIME ONLY BY THE OPTIONEE (OR BY THE OPTIONEE'S GUARDIAN OR PERSONAL REPRESENTATIVE IN THE EVENT OF THE OPTIONEE'S INCAPACITY). THE OPTIONEE MAY ELECT TO DESIGNATE A BENEFICIARY BY PROVIDING WRITTEN NOTICE OF THE NAME OF SUCH BENEFICIARY TO THE COMPANY, AND MAY REVOKE OR CHANGE SUCH DESIGNATION AT ANY TIME BY FILING WRITTEN NOTICE OF REVOCATION OR CHANGE WITH THE COMPANY; SUCH BENEFICIARY MAY EXERCISE THE OPTIONEE'S STOCK OPTION IN THE EVENT OF THE OPTIONEE'S DEATH TO THE EXTENT PROVIDED HEREIN. IF THE OPTIONEE DOES NOT DESIGNATE A BENEFICIARY, OR IF THE DESIGNATED BENEFICIARY PREDECEASES THE OPTIONEE, THE LEGAL REPRESENTATIVE OF THE OPTIONEE MAY EXERCISE THIS STOCK OPTION TO THE EXTENT PROVIDED HEREIN IN THE EVENT OF THE OPTIONEE'S DEATH.

SECTION 29. RESTRICTIONS ON TRANSFER OF SHARES. THE SHARES ACQUIRED UPON EXERCISE OF THE STOCK OPTION SHALL BE SUBJECT TO CERTAIN TRANSFER RESTRICTIONS AND OTHER LIMITATIONS INCLUDING, WITHOUT LIMITATION, THE PROVISIONS CONTAINED IN SECTION 9 OF THE PLAN.

SECTION 30. MISCELLANEOUS PROVISIONS.

(a) Equitable Relief. The parties hereto agree and declare that legal remedies may be inadequate to enforce the provisions of this Agreement and that equitable relief, including specific performance and injunctive relief, may be used to enforce the provisions of this Agreement.

(b) Adjustments for Changes in Capital Structure. If, as a result of any reorganization, recapitalization, reincorporation, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Common Stock, the outstanding shares of Common Stock are increased or decreased or are exchanged for a different number or kind of securities of the Company, the restrictions contained in this Agreement shall apply with equal force to additional and/or substitute securities, if any, received by the Optionee in exchange for, or by virtue of his or her ownership of, this Stock Option or Shares acquired pursuant thereto.

(c) Change and Modifications. This Agreement may not be orally changed, modified or terminated, nor shall any oral waiver of any of its terms be effective. This Agreement may be changed, modified or terminated only by an agreement in writing signed by the Company and the Optionee.

(d) Governing Law. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts.

(e) Headings. The headings are intended only for convenience in finding the subject matter and do not constitute part of the text of this Agreement and shall not be considered in the interpretation of this Agreement.

(f) Saving Clause. If any provision(s) of this Agreement shall be determined to be illegal or unenforceable, such determination shall in no manner affect the legality or enforceability of any other provision hereof.

(g) Notices. All notices, requests, consents and other communications shall be in writing and be deemed given when delivered personally, by telex or facsimile transmission or when received if mailed by first class registered or certified mail, postage prepaid. Notices to the Company or the Optionee shall be addressed as set forth underneath their signatures below, or to such other address or addresses as may have been furnished by such party in writing to the other.

(h) Benefit and Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their respective successors, assigns, and legal representatives. The Company has the right to assign this Agreement, and such assignee shall become entitled to all the rights of the Company hereunder to the extent of such assignment.

(i) Counterparts. For the convenience of the parties and to facilitate execution, this Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same document.

(j) Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 31. DISPUTE RESOLUTION.

(a) Except as provided below, any dispute arising out of or relating to the Plan or this Stock Option, this Agreement, or the breach, termination or validity of the Plan, this Stock Option or this Agreement, shall be finally settled by binding arbitration conducted expeditiously in accordance with the J.A.M.S./Endispute Comprehensive Arbitration Rules and Procedures (the "J.A.M.S. Rules"). The arbitration shall be governed by the United States Arbitration Act, 9 U.S.C. Sections 1-16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The place of arbitration shall be Boston, Massachusetts.

(b) The arbitration shall commence within 60 days of the date on which a written demand for arbitration is filed by any party hereto. In connection with the arbitration proceeding, the arbitrator shall have the power to order the production of documents by each party and any third-party witnesses. In addition, each party may take up to three depositions as of right, and the arbitrator may in his or her discretion allow additional depositions upon good cause shown by the moving party. However, the arbitrator shall not have the power to order the answering of interrogatories or the response to requests for admission. In connection with any arbitration, each party to the arbitration shall provide to the other, no later than seven business days before the date of the arbitration, the identity of all persons that may testify at the arbitration and a copy of all documents that may be introduced at the arbitration or considered or used by a party's witness or expert. The arbitrator's decision and award shall be made and delivered within six months of the selection of the arbitrator. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages, and each party hereby irrevocably waives any claim to such damages.

(c) The Company, the Optionee, each party to the Agreement and any other holder of Shares issued pursuant to this Agreement (each, a "Party") covenants and agrees that such party will participate in the arbitration in good faith. This Section 7 applies equally to requests for temporary, preliminary or permanent injunctive relief, except that in the case of temporary or preliminary injunctive relief any party may proceed in court without prior arbitration for the limited purpose of avoiding immediate and irreparable harm.

(d) Each Party (i) hereby irrevocably submits to the jurisdiction of any United States District Court of competent jurisdiction for the purpose of enforcing the award or decision in any such proceeding, (ii) hereby waives, and agrees not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above named courts, that its property is exempt or immune from attachment or

execution (except as protected by applicable law), that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (iii) hereby waives and agrees not to seek any review by any court of any other jurisdiction which may be called upon to grant an enforcement of the judgment of any such court. Each Party hereby consents to service of process by registered mail at the address to which notices are to be given. Each Party agrees that its, his or her submission to jurisdiction and its, his or her consent to service of process by mail is made for the express benefit of each other Party. Final judgment against any Party in any such action, suit or proceeding may be enforced in other jurisdictions by suit, action or proceeding on the judgment, or in any other manner provided by or pursuant to the laws of such other jurisdiction.

SECTION 32. WAIVER OF STATUTORY INFORMATION RIGHTS. THE OPTIONEE UNDERSTANDS AND AGREES THAT, BUT FOR THE WAIVER MADE HEREIN, THE OPTIONEE WOULD BE ENTITLED, UPON WRITTEN DEMAND UNDER OATH STATING THE PURPOSE THEREOF, TO INSPECT FOR ANY PROPER PURPOSE, AND TO MAKE COPIES AND EXTRACTS FROM, THE COMPANY'S STOCK LEDGER, A LIST OF ITS STOCKHOLDERS, AND ITS OTHER BOOKS AND RECORDS, AND THE BOOKS AND RECORDS OF SUBSIDIARIES OF THE COMPANY, IF ANY, UNDER THE CIRCUMSTANCES AND IN THE MANNER PROVIDED IN SECTION 220 OF THE GENERAL CORPORATION LAW OF DELAWARE (ANY AND ALL SUCH RIGHTS, AND ANY AND ALL SUCH OTHER RIGHTS OF THE OPTIONEE AS MAY BE PROVIDED FOR IN SECTION 220, THE "INSPECTION RIGHTS"). IN LIGHT OF THE FOREGOING, UNTIL THE FIRST SALE OF STOCK OF THE COMPANY TO THE GENERAL PUBLIC PURSUANT TO A REGISTRATION STATEMENT FILED WITH AND DECLARED EFFECTIVE BY THE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES ACT, THE OPTIONEE HEREBY UNCONDITIONALLY AND IRREVOCABLY WAIVES THE INSPECTION RIGHTS, WHETHER SUCH INSPECTION RIGHTS WOULD BE EXERCISED OR PURSUED DIRECTLY OR INDIRECTLY PURSUANT TO SECTION 220 OR OTHERWISE, AND COVENANTS AND AGREES NEVER TO DIRECTLY OR INDIRECTLY COMMENCE, VOLUNTARILY AID IN ANY WAY, PROSECUTE, ASSIGN, TRANSFER, OR CAUSE TO BE COMMENCED ANY CLAIM, ACTION, CAUSE OF ACTION, OR OTHER PROCEEDING TO PURSUE OR EXERCISE THE INSPECTION RIGHTS. THE FOREGOING WAIVER SHALL NOT AFFECT ANY RIGHTS OF A DIRECTOR, IN HIS OR HER CAPACITY AS SUCH, UNDER SECTION 220. THE FOREGOING WAIVER SHALL NOT APPLY TO ANY CONTRACTUAL INSPECTION RIGHTS OF THE OPTIONEE UNDER ANY OTHER WRITTEN AGREEMENT BETWEEN THE OPTIONEE AND THE COMPANY.

[SIGNATURE PAGE FOLLOWS]

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned as of the date first above written.

BICARA THERAPEUTICS INC.

By: _____

Name:

Title:

Address:

The undersigned hereby acknowledges receiving and reviewing a copy of the Plan, including, without limitation, Section 9 thereof, and understands that this Stock Option is subject to the terms of the Plan and of this Agreement. This Agreement is hereby accepted, and the terms and conditions of the Plan, the Grant Notice and this Agreement, SPECIFICALLY INCLUDING THE ARBITRATION PROVISIONS SET FORTH IN SECTION 7 AND THE WAIVER OF STATUTORY INFORMATION RIGHTS SET FORTH IN SECTION 8 OF THIS AGREEMENT, are hereby agreed to, by the undersigned as of the date first above written.

OPTIONEE:

Name:

Address:

[SPOUSE'S CONSENT⁴

I acknowledge that I have read the
foregoing Non-Qualified Stock Option Agreement
and understand the contents thereof.

_____]

⁴ A spouse's consent is recommended only if the Optionee's state of residence is one of the following community property states: Arizona, California, Idaho, Louisiana, Nevada, New Mexico, Texas, Washington and Wisconsin.

DESIGNATED BENEFICIARY:

Beneficiary's Address:

Appendix A

STOCK OPTION EXERCISE NOTICE

Bicara Therapeutics Inc.
Attention: [_____]

Pursuant to the terms of the grant notice and stock option agreement between the undersigned and Bicara Therapeutics Inc. (the "Company") dated _____ (the "Agreement") under the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan, I, [Insert Name] _____, hereby [Circle One] partially/fully exercise such option by including herein payment in the amount of \$ _____ representing the purchase price for [Fill in number of Shares] _____ Shares. I have chosen the following form(s) of payment:

- 1. Cash
- 2. Certified or bank check payable to Bicara Therapeutics Inc.
- 3. Other (as referenced in the Agreement and described in the Plan (please describe))
_____.

In connection with my exercise of the option as set forth above, I hereby represent and warrant to the Company as follows:

- (i) I am purchasing the Shares for my own account for investment only, and not for resale or with a view to the distribution thereof.
- (ii) I have had such an opportunity as I have deemed adequate to obtain from the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company and have consulted with my own advisers with respect to my investment in the Company.
- (iii) I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
- (iv) I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period of time.
- (v) I understand that the Shares may not be registered under the Securities Act of 1933 (it being understood that the Shares are being issued and sold in reliance on the exemption provided in Rule 701 thereunder) or any applicable state securities or "blue sky" laws and may not be sold or otherwise transferred or disposed of in the absence of an effective registration statement under the Securities Act of 1933 and under any applicable state securities or "blue sky" laws (or exemptions from the registration requirement thereof). I further acknowledge that certificates representing Shares will bear restrictive legends reflecting the foregoing and/or that book entries for uncertificated Shares will include similar restrictive notations.

(vi) I have read and understand the Plan and acknowledge and agree that the Shares are subject to all of the relevant terms of the Plan, including without limitation, the transfer restrictions set forth in Section 9 of the Plan.

(vii) I understand and agree that the Company has a right of first refusal with respect to the Shares pursuant to Section 9(b) of the Plan.

(viii) I understand and agree that the Company has certain repurchase rights with respect to the Shares pursuant to Section 9(c) of the Plan.

(ix) I understand and agree that I may not sell or otherwise transfer or dispose of the Shares for a period of time following the effective date of a public offering by the Company as described in Section 9(f) of the Plan.

(x) I understand and agree to the waiver of statutory information rights as set forth in Section 8 of the Agreement.

Sincerely yours,

Name:

Address:

Date: _____

**RESTRICTED STOCK AWARD NOTICE
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

Pursuant to the Bicara Therapeutics Inc. 2019 Stock Option and Grant Plan (the "Plan"), Bicara Therapeutics Inc., a Delaware corporation (together with any successor, the "Company"), hereby grants, sells and issues to the individual named below, the Shares at the Per Share Purchase Price, subject to the terms and conditions set forth in this Restricted Stock Award Notice (the "Award Notice"), the attached Restricted Stock Agreement (the "Agreement") and the Plan. The Grantee agrees to the provisions set forth herein and acknowledges that each such provision is a material condition of the Company's agreement to issue and sell the Shares to him or her. The Company hereby acknowledges receipt of \$[_____] in full payment for the Shares. All references to share prices and amounts herein shall be equitably adjusted to reflect stock splits, stock dividends, recapitalizations, mergers, reorganizations and similar changes affecting the capital stock of the Company, and any shares of capital stock of the Company received on or in respect of Shares in connection with any such event (including any shares of capital stock or any right, option or warrant to receive the same or any security convertible into or exchangeable for any such shares or received upon conversion of any such shares) shall be subject to this Agreement on the same basis and extent at the relevant time as the Shares in respect of which they were issued, and shall be deemed Shares as if and to the same extent they were issued at the date hereof.

Name of Grantee: _____ (the "Grantee")
No. of Shares: _____ Shares of Common Stock (the "Shares")
Grant Date: _____, ____
Date of Purchase of Shares: _____, ____
Vesting Commencement Date: _____, ____ (the "Vesting Commencement Date")
Per Share Purchase Price: \$ _____ (the "Per Share Purchase Price")

Vesting Schedule:

25% of the Shares shall vest on the [first] anniversary of the Vesting Commencement Date; provided that the Grantee remains an employee of the Company or any Affiliate at such time. Thereafter, the remaining 75% of the Shares shall vest in 12 equal quarterly installments following the first anniversary of the Vesting Commencement Date, provided the Grantee remains an employee of the Company or any Affiliate at such time.

Notwithstanding anything in the Agreement to the contrary in the case of a Sale Event, the Shares of Restricted Stock shall be treated as provided in Section 3(c) of the Plan [provided; however INSERT ANY ACCELERATED VESTING PROVISION HERE].

Attachments: Restricted Stock Agreement, 2019 Stock Option and Grant Plan

**RESTRICTED STOCK AGREEMENT
UNDER THE BICARA THERAPEUTICS INC.
2019 STOCK OPTION AND GRANT PLAN**

All capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Award Notice and the Plan.

2. PURCHASE AND SALE OF SHARES; VESTING; INVESTMENT REPRESENTATIONS.

(a) Purchase and Sale. The Company hereby sells to the Grantee, and the Grantee hereby purchases from the Company, the number of Shares set forth in the Award Notice for the Per Share Purchase Price.

(b) Vesting. Initially, all of the Shares are non-transferable and subject to a substantial risk of forfeiture and are Shares of Restricted Stock. The risk of forfeiture shall lapse with respect to the Shares on the respective dates indicated on the Vesting Schedule set forth in the Award Notice.

(c) Investment Representations. In connection with the purchase and sale of the Shares contemplated by Section 1(a) above, the Grantee hereby represents and warrants to the Company as follows:

(i) The Grantee is purchasing the Shares for the Grantee's own account for investment only, and not for resale or with a view to the distribution thereof.

(ii) The Grantee has had such an opportunity as he or she has deemed adequate to obtain from the Company such information as is necessary to permit him or her to evaluate the merits and risks of the Grantee's investment in the Company and has consulted with the Grantee's own advisers with respect to the Grantee's investment in the Company.

(iii) The Grantee has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

(iv) The Grantee can afford a complete loss of the value of the Shares and is able to bear the economic risk of holding such Shares for an indefinite period.

(v) The Grantee understands that the Shares are not registered under the Act (it being understood that the Shares are being issued and sold in reliance on the exemption provided in Rule 701 thereunder) or any applicable state securities or "blue sky" laws and may not be sold or otherwise transferred or disposed of in the absence of an effective registration statement under the Act and under any applicable state securities or "blue sky" laws (or exemptions from the registration requirements thereof). The Grantee further acknowledges that certificates representing the Shares will bear restrictive legends reflecting the foregoing and/or that book entries for uncertificated Shares will include similar restrictive notations.

(vi) The Grantee has read and understands the Plan and acknowledges and agrees that the Shares are subject to all of the relevant terms of the Plan, including without limitation, the transfer restrictions set forth in Section 9 of the Plan.

(vii) The Grantee understands and agrees that the Company has a right of first refusal with respect to the Shares pursuant to Section 9(b) of the Plan.

(viii) The Grantee understands and agree that the Company has certain repurchase rights with respect to the Shares pursuant to Section 9(c) of the Plan.

(ix) The Grantee understands and agrees that the Grantee may not sell or otherwise transfer or dispose of the Shares for a period of time following the effective date of a public offering by the Company as described in Section 9(f) of the Plan.

3. REPURCHASE RIGHT UPON A TERMINATION EVENT. THE COMPANY SHALL HAVE THE RIGHT TO REPURCHASE SHARES OF RESTRICTED STOCK THAT ARE UNVESTED AS OF THE DATE OF SUCH TERMINATION EVENT AS SET FORTH IN SECTION 9(C) OF THE PLAN. FOR PURPOSES OF THIS AGREEMENT, A "TERMINATION EVENT" SHALL MEAN TERMINATION OF THE GRANTEE'S EMPLOYMENT WITH THE COMPANY AND ANY AFFILIATE.
4. RESTRICTIONS ON TRANSFER OF SHARES. THE SHARES (WHETHER OR NOT VESTED) SHALL BE SUBJECT TO CERTAIN TRANSFER RESTRICTIONS AND OTHER LIMITATIONS INCLUDING, WITHOUT LIMITATION, THE PROVISIONS CONTAINED IN SECTION 9 OF THE PLAN
5. INCORPORATION OF PLAN. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THIS RESTRICTED STOCK AWARD SHALL BE SUBJECT TO AND GOVERNED BY ALL THE TERMS AND CONDITIONS OF THE PLAN.
6. MISCELLANEOUS PROVISIONS.

(a) Record Owner; Dividends. The Grantee and any Permitted Transferees, during the duration of this Agreement, shall be considered the record owners of and shall be entitled to vote the Shares if and to the extent the Shares are entitled to voting rights. The Grantee and any Permitted Transferees shall be entitled to receive all dividends and any other distributions declared on the Shares; provided, however, that the Company is under no duty to declare any such dividends or to make any such distribution.

(b) Section 83(b) Election. The Grantee shall consult with the Grantee's tax advisor to determine whether it would be appropriate for the Grantee to make an election under Section 83(b) of the Code with respect to this Award. Any such election must be filed with the Internal Revenue Service within 30 days of the date of this Award. If the Grantee makes an election under Section 83(b) of the Code, the Grantee shall give prompt notice to the Company (and provide a copy of such election to the Company). A sample Section 83(b) election is attached to this Agreement as Exhibit A.

(c) Equitable Relief. The parties hereto agree and declare that legal remedies may be inadequate to enforce the provisions of this Agreement and that equitable relief, including specific performance and injunctive relief, may be used to enforce the provisions of this Agreement.

(d) Change and Modifications. This Agreement may not be orally changed, modified or terminated, nor shall any oral waiver of any of its terms be effective. This Agreement may be changed, modified or terminated only by an agreement in writing signed by the Company and the Grantee.

(e) Governing Law. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts.

(f) Headings. The headings are intended only for convenience in finding the subject matter and do not constitute part of the text of this Agreement and shall not be considered in the interpretation of this Agreement.

(g) Saving Clause. If any provision(s) of this Agreement shall be determined to be illegal or unenforceable, such determination shall in no manner affect the legality or enforceability of any other provision hereof.

(h) Notices. All notices, requests, consents and other communications shall be in writing and be deemed given when delivered personally, by telex or facsimile transmission or when received if mailed by first class registered or certified mail, postage prepaid. Notices to the Company or the Grantee shall be addressed as set forth underneath their signatures below, or to such other address or addresses as may have been furnished by such party in writing to the other.

(i) Benefit and Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their respective successors, assigns, and legal representatives. The Company has the right to assign this Agreement, and such assignee shall become entitled to all the rights of the Company hereunder to the extent of such assignment.

(j) Counterparts. For the convenience of the parties and to facilitate execution, this Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same document.

(k) Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

(a) Except as provided below, any dispute arising out of or relating to the Plan or the Shares, this Agreement, or the breach, termination or validity of the Plan, the Shares or this Agreement, shall be finally settled by binding arbitration conducted expeditiously in accordance with the J.A.M.S./Endispute Comprehensive Arbitration Rules and Procedures (the "J.A.M.S. Rules"). The arbitration shall be governed by the United States Arbitration Act, 9 U.S.C. Sections 1—16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The place of arbitration shall be Boston, Massachusetts.

(b) The arbitration shall commence within 60 days of the date on which a written demand for arbitration is filed by any party hereto. In connection with the arbitration proceeding, the arbitrator shall have the power to order the production of documents by each party and any third-party witnesses. In addition, each party may take up to three depositions as of right, and the arbitrator may in his or her discretion allow additional depositions upon good cause shown by the moving party. However, the arbitrator shall not have the power to order the answering of interrogatories or the response to requests for admission. In connection with any arbitration, each party to the arbitration shall provide to the other, no later than seven business days before the date of the arbitration, the identity of all persons that may testify at the arbitration and a copy of all documents that may be introduced at the arbitration or considered or used by a party's witness or expert. The arbitrator's decision and award shall be made and delivered within six months of the selection of the arbitrator. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages, and each party hereby irrevocably waives any claim to such damages.

(c) The Company, the Grantee, each party to the Agreement and any other holder of Shares issued pursuant to this Agreement (each, a "Party") covenants and agrees that such party will participate in the arbitration in good faith. This Section 6 applies equally to requests for temporary, preliminary or permanent injunctive relief, except that in the case of temporary or preliminary injunctive relief any party may proceed in court without prior arbitration for the limited purpose of avoiding immediate and irreparable harm.

(d) Each Party (i) hereby irrevocably submits to the jurisdiction of any United States District Court of competent jurisdiction for the purpose of enforcing the award or decision in any such proceeding, (ii) hereby waives, and agrees not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above named courts, that its property is exempt or immune from attachment or execution (except as protected by applicable law), that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (iii) hereby waives and agrees not to seek any review by any court of any other jurisdiction which may be called upon to grant an enforcement of the judgment of any such court. Each Party hereby consents to service of process by registered mail at the address to which notices are to be given. Each Party agrees that its, his or her submission to jurisdiction and its, his or her consent to service of process by mail is made for the express benefit of each other Party. Final judgment against any Party in any such action, suit or proceeding may be enforced in other jurisdictions by suit, action or proceeding on the judgment, or in any other manner provided by or pursuant to the laws of such other jurisdiction.

8. WAIVER OF STATUTORY INFORMATION RIGHTS. THE GRANTEE UNDERSTANDS AND AGREES THAT, BUT FOR THE WAIVER MADE HEREIN, THE GRANTEE WOULD BE ENTITLED, UPON WRITTEN DEMAND UNDER OATH STATING THE PURPOSE THEREOF, TO INSPECT FOR ANY PROPER PURPOSE, AND TO MAKE COPIES AND EXTRACTS FROM, THE COMPANY'S STOCK LEDGER, A LIST OF ITS STOCKHOLDERS, AND ITS OTHER BOOKS AND RECORDS, AND THE BOOKS AND RECORDS OF SUBSIDIARIES OF THE COMPANY, IF ANY, UNDER THE CIRCUMSTANCES AND IN THE MANNER PROVIDED IN SECTION 220 OF THE GENERAL CORPORATION LAW OF DELAWARE (ANY AND ALL SUCH RIGHTS, AND ANY AND ALL SUCH OTHER RIGHTS OF THE GRANTEE AS MAY BE PROVIDED FOR IN SECTION 220, THE "INSPECTION RIGHTS"), IN LIGHT OF THE FOREGOING, UNTIL THE FIRST SALE OF STOCK OF THE COMPANY TO THE GENERAL PUBLIC PURSUANT TO A REGISTRATION STATEMENT FILED WITH AND DECLARED EFFECTIVE BY THE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES ACT, THE GRANTEE HEREBY UNCONDITIONALLY AND IRREVOCABLY WAIVES THE INSPECTION RIGHTS, WHETHER SUCH INSPECTION RIGHTS WOULD BE EXERCISED OR PURSUED DIRECTLY OR INDIRECTLY PURSUANT TO SECTION 220 OR OTHERWISE, AND COVENANTS AND AGREES NEVER TO DIRECTLY OR INDIRECTLY COMMENCE, VOLUNTARILY AID IN ANY WAY, PROSECUTE, ASSIGN, TRANSFER, OR CAUSE TO BE COMMENCED ANY CLAIM, ACTION, CAUSE OF ACTION, OR OTHER PROCEEDING TO PURSUE OR EXERCISE THE INSPECTION RIGHTS. THE FOREGOING WAIVER SHALL NOT AFFECT ANY RIGHTS OF A DIRECTOR, IN HIS OR HER CAPACITY AS SUCH, UNDER SECTION 220. THE FOREGOING WAIVER SHALL NOT APPLY TO ANY CONTRACTUAL INSPECTION RIGHTS OF THE GRANTEE UNDER ANY OTHER WRITTEN AGREEMENT BETWEEN THE GRANTEE AND THE COMPANY.

[SIGNATURE PAGE FOLLOWS]

The foregoing Restricted Stock Agreement is hereby accepted and the terms and conditions thereof are hereby agreed to by the undersigned as of the date of purchase of Shares above written.

BICARA THERAPEUTICS INC.

By: _____
Name: _____
Title: _____

Address: _____

The undersigned hereby acknowledges receiving and reviewing a copy of the Plan, including, without limitation, Section 9 thereof and understands that the Shares granted hereby are subject to the terms of the Plan and of this Agreement. This Agreement is hereby accepted, and the terms and conditions of the Plan, the Award Notice and this Agreement, SPECIFICALLY INCLUDING THE ARBITRATION PROVISIONS SET FORTH IN SECTION 6 AND THE WAIVER OF STATUTORY INFORMATION RIGHTS SET FORTH IN SECTION 7 OF THIS AGREEMENT, are hereby agreed to, by the undersigned as of the date first above written.

GRANTEE:

Name: _____

Address: _____

[SPOUSE'S CONSENT⁵

I acknowledge that I have read the
foregoing Restricted Stock Agreement
and understand the contents thereof.

_____]

⁵ A spouse's consent is required only if the Grantee's state of residence is one of the following community property states: Arizona, California, Idaho, Louisiana, New Mexico, Nevada, Texas, Washington and Wisconsin.

CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(B)(10) AND REPLACED WITH [*]. SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

CONTRACT TRANSFER AND LICENSE AGREEMENT

This Contract Transfer and License Agreement (the “**License Agreement**” or “**Agreement**”) is made on October 1, 2019 by and between **Biocon Limited**, a company duly incorporated under the laws of India having a principal place of business at 20th KM., Hosur Road, Electronics City P.O, Bangalore-560100, India (“**Biocon**”) and **Bicara Therapeutics Inc.**, a company duly incorporated under the laws of Delaware having a principal place of business at 245 Main Street, Cambridge, MA 02142, County of Middlesex (“**Bicara**”).

RECITALS

- A. WHEREAS, Biocon owns or controls certain patents, patent applications, proprietary know-how, scientific and technical information relating to certain Products (as defined below);
- B. WHEREAS, Bicara is in the business of research, development, and commercialization of products in the Field and desires to receive a license under such intellectual property rights and an assignment of certain contracts related to the Products; and
- C. WHEREAS, Biocon desires to grant Bicara a license to research, develop, manufacture and commercialize the Products in the Territory and to assign such contracts to Bicara.

NOW, THEREFORE, in consideration of the mutual covenants, representations and warranties made herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

Article 1 Definitions and Interpretation

As used in this License Agreement, the capitalized terms have the meaning given thereto in this Article 1 or elsewhere in this License Agreement:

- 1.1 “**Affiliate**” means, with respect a particular Party, a person, corporation, firm or other entity that controls, is controlled by or is under common control with such Party, for so long as such control exists. For the purposes of this definition, “control” means the actual power, either directly or indirectly to direct or cause the direction of the management and policies of such person, corporation, firm or other entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such corporation, firm or other entity, or by contractual arrangement or otherwise. Notwithstanding the foregoing, for the purpose of this License Agreement, Biocon and Bicara are not to be considered as Affiliates.
- 1.2 “**Applicable Laws**” means any and all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing), policies, and other requirements of any applicable governmental authority that govern or otherwise apply to a Party’s activities in connection with this Agreement.

- 1.3 “**Assumed Contracts**” means those contracts entered into by Biocon that are listed in Schedule 1.3 to this License Agreement.
- 1.4 “**Biocon Know-How**” means any and all Know-How Controlled by Biocon or its Affiliates as of the Effective Date or at any time during the Capture Period (other than Arising IP) that is necessary or reasonably useful to practice the subject matter of the Biocon Patents or to make use, sell, offer to sell, import and otherwise exploit Products.
- 1.5 “**Biocon Materials**” means the following information and materials: (a) [***]; (b) [***], each as detailed in Schedule 1.5 to this Agreement.
- 1.6 “**Biocon Patents**” means any and all patents or patent applications owned or Controlled by Biocon or its Affiliates as of the Effective- Date or at any time during the Capture Period (other than Arising IP) that Cover a Product or Biocon Materials, including those patents and patent applications listed in Schedule 1.6, and any patents issuing therefrom and any divisions, continuations, continuations-in-part (to the extent claiming the same subject matter), reissues, renewals, substitutions, extensions, registrations, reexaminations, revalidations, supplementary protection certificates and the like of any patents and patent applications thereof, including any foreign counterparts to any of the foregoing. Any additional patents and patent applications Controlled by Biocon or its Affiliates during the Capture Period that Cover a Product or the Biocon Materials shall automatically be added to Schedule 1.6 and be included in the Biocon Patents.
- 1.7 “**Biocon Technologies**” means collectively; the Biocon Materials, Biocon Know-How, and Biocon Patents.
- 1.8 “**Business Days**” means any day other than a Saturday, Sunday, or any other day on which commercial banks in Bangalore, India or Boston, Massachusetts are authorized or required by law to remain closed.
- 1.9 “**Capture Period**” means the period from [***] until [***]; provided that the Capture Period [***].
- 1.10 “**Confidential Information**” of a Party (the “**Disclosing Party**”) means and includes, without limitation, any and all technical and non-technical information and material disclosed by or on behalf of the Disclosing Party to the other Party (the “**Receiving Party**”) or its Affiliates or its or their respective employees, officers, directors or representatives in connection with this Agreement, including, but not limited to, Know-How, trade secrets, Biocon Technology, and other non-public technical/process/scientific information regarding study, drug, research, experimental work, clinical development plans, protocols, drug delivery regimens, and equipment, whether tangible or intangible, and whether stored or compiled physically, electronically, digitally, graphically, photographically, or in writing, that is either marked “Confidential” or “Proprietary,” or is known, or reasonably should be known, by the Receiving Party to be confidential. The terms of this Agreement are the Confidential Information of both Parties.

- 1.11 “**Control**” or “**Controlled**” means, (a) with respect to materials, data or information, physical possession or the right to such physical possession of those items, and (b) with respect to intellectual property rights or Know-How, possession of the power and authority, whether arising by ownership, license, or other authorization, to grant and authorize the assignments, licenses or sublicenses, as applicable, under such intellectual property rights or Know-How of the scope granted under this Agreement.
- 1.12 “**Cover**” means, with respect to any subject matter, that the manufacture, use, sale, offering for sale, importation, exportation, or other exploitation of such subject matter that would infringe a claim of a patent or patent application at the time thereof absent ownership or license therein or thereto, as applicable. For clarity, with respect to a claim within a patent application, “Cover” includes a claim in such patent application if such claim were issued as then prosecuted. “Covered” and “Covering” shall have correlative meanings.
- 1.13 “**Effective Date**” has the meaning set forth in the preamble.
- 1.14 “**Field**” means [***].
- 1.15 “**Know-How**” means any and all materials, technology, data, results, technical and scientific information, specifications, instructions, processes, formulae, methods, protocols, inventions, knowledge, ideas, developments, sequences, techniques, compositions, chemistries, algorithms, research, modifications, improvements, discoveries, know-how, expertise and trade secrets, and any intellectual property rights embodying any of the foregoing, but excluding any patent rights.
- 1.16 “**Marketing Approval**” means, with respect to Product for an indication within the Field, in a particular jurisdiction, approval by the Regulatory Authority of any application (including supplements, amendments, pre- and post-approvals and price approvals) for initiating commercialization of such Product in such jurisdiction, including any price approval or reimbursement as may be reasonably necessary to market or sell such Product in such jurisdiction.
- 1.17 “**Party**” or “**Parties**” means and refers to Biocon and/or Bicara individually, or collectively, as the context permits.
- 1.18 “**Product**” means [***]. For clarity, Product shall include drug substance, formulations, delivery device in any form or dosage. Products shall include, without limitation, the product candidates referred to by Biocon as [***] (such product candidates collectively, the “Product Candidates”) as of the Effective Date, each as set forth in more detail on Schedule 1.18.
- 1.19 “**Regulatory Approval**” means, with respect to the Product within the Field in a jurisdiction, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary in order to import, export, develop, conduct clinical trials, manufacture, sell, offer for sale, or market the Product in such jurisdiction including Marketing Approval.

- 1.20 “**Regulatory Authority**” means, with respect to a particular country, any federal, national, multinational, state, provincial or local regulatory agency, department, bureau, or other governmental entity with authority over the development, manufacture, commercialization, including granting of Marketing Approvals with respect to Product including the Drugs Controller General of India (DCGI), European Medicines Agency (EMA), the United States Food and Drug Administration (FDA), and, in each case, any successor entity thereto.
- 1.21 “**Territory**” shall mean [***].
- 1.22 “**Third Party**” means any entity other than Biocon or Bicara or any of their respective Affiliates.

Article 2 License and Transfer of Assumed Contracts,

- 2.1 Subject to the terms and conditions of this License Agreement, Biocon hereby grants to Bicara an [***] license, with the right to grant and authorize sublicenses (subject to Section 2.2), under the Biocon Technology, to make, use, sell, offer to sell, import, and otherwise exploit Products in the Field.
- 2.2 Notwithstanding anything contrary contained herein, [***] with the provisions of this License Agreement.
- 2.3 To the extent there is any inconsistency between Bicara’s obligations to the counterparties under the Assumed Contracts and Bicara’s obligations to Biocon under this License Agreement, the [***] shall prevail and [***] shall not be deemed to be in breach of [***] by acting in accordance with the provisions of [***].
- 2.4 Except as expressly set forth herein, no right or license under any information, patent rights or other intellectual property rights is granted or shall be granted by implication. All rights or licenses are or shall be granted only as expressly provided in the terms of this License Agreement.
- 2.5 **Assignment of Assumed Contracts.** Biocon hereby assigns to Bicara, and Bicara hereby assumes, the Assumed Contracts. Bicara shall perform and fulfil all obligations of Biocon under the Assumed Contracts with effect from the Effective Date. Biocon and Bicara shall send out a notice of assignment to the counterparties of Assumed Contracts. To the extent that any of the Assumed Contracts cannot be assigned to Bicara without the consent of the relevant counterparty, Biocon shall use reasonable endeavors to obtain such consent.
- 2.6 **Transition Arrangement.** Until each Assumed Contract has been assigned to Bicara:
- (i) Biocon shall hold the benefit of that Assumed Contract in trust for Bicara, exercise its rights as Bicara may direct or approve in writing, and account to Bicara for any sums (or other benefits) which arise under such Assumed Contract;
 - (ii) Biocon shall continue to be responsible to perform and discharge the obligations under the relevant Assumed Contract, but in doing so Biocon shall act only in accordance with Bicara’s written directions and Bicara will cooperate in Biocon’s transfer of the Assumed Contracts to Bicara;

(iii) [***] shall [***] any costs and expenses which [***] shall properly and reasonably incur (in accordance with [***] written instructions) and, subject to Section 5.3, indemnify and hold harmless [***] against [***] Losses properly and reasonably incurred by [***] and arising from any Third Party claim, action or proceeding, in each case in connection [***], except to the extent arising from [***].

- 2.7 Without limiting Sections 2.5 and 2.6 above, if Biocon is unable to obtain the necessary consent to assign to Bicara an Assumed Contract, Biocon agrees to cooperate with Bicara, as reasonably requested in writing by Bicara, to enter directly into a corresponding agreement to which Bicara is a party, upon execution of which such agreement that Biocon is unable to assign shall cease to be an Assumed Contract.

Article 3 Development and Commercialization.

- 3.1 Subject to the terms and conditions of this Agreement, as between the Parties, Bicara, at its own expense, cost, and consequences, and further in compliance with all Applicable Laws, shall be responsible for research, development, manufacturing, and commercialization of Product, including obtaining Marketing Approvals and other Regulatory Approvals in its own name and in its discretion in the Territory.
- 3.2 Subject to the terms and conditions of this Agreement, as between the Parties, [***] shall be solely responsible for all costs and consequences, including any suits, demands, penalties, and liabilities, including any claims with respect to intellectual property infringement, product liability or product recall associated with its exploitation of the Products. [***] shall satisfy all such claims without prejudice and without recourse to [***], except to the extent such claims arise from breach of this Agreement by [***] negligence or willful misconduct.
- 3.3 Subject to the terms and conditions of this Agreement, within [***] days after the Effective Date, Biocon shall transfer to Bicara all Biocon Know-How and Biocon Materials in existence as of the Effective Date. Thereafter during the Capture Period, [***] Biocon shall deliver to Bicara any additional Biocon Materials or Biocon Know-How that comes into the possession or Control of Biocon or its Affiliates. The mode of such transfer shall be as mutually determined by the Parties in good faith with the goal of efficiency and cost effectiveness.

Article 4 Intellectual Property Rights.

- 4.1 **Arising IP.** As between the Parties, [***] shall own all rights, title and interest in any and all inventions, discoveries, technology, subject matter conceived, developed or reduced to practice by Bicara with respect to subject matter of this License Agreement or otherwise resulting from the activities of Bicara in exercising its rights under this license Agreement (collectively “**Arising IP**”). [***]

- 4.2 **Registration of License.** Bicara undertakes to use commercially reasonable efforts to take all steps necessary and to bear all related costs, fees, and duties: (i) to register itself as licensee of the Product, Biocon Materials and the Regulatory Approvals, when so required by Applicable Law; and (ii) to complete all other necessary formalities (such as delivery of all necessary signatures, documents and information) requested in the respective countries by any governmental authority in relation to the licenses granted under this License Agreement.
- 4.3 **Prosecution and Maintenance of Biocon Patents.** Following the Effective Date, Bicara shall have the sole right to prosecute and maintain and shall use commercially reasonable efforts to prosecute and maintain any Biocon Patents in the Territory, in Biocon's name and at [***] sole cost and expense using counsel reasonably acceptable to Biocon. Bicara shall consult with Biocon as to the prosecution and maintenance of Biocon Patents in the Territory and shall provide Biocon copies of relevant drafts and documents in advance of such consultation. Bicara shall periodically update the status of such prosecution and maintenance of Biocon Patents in the Territory and shall provide to Biocon copies of all relevant filings including correspondence with patent office within [***] days of filing. Bicara shall consider the comments of Biocon in good faith. Biocon shall provide Bicara all reasonable assistance and cooperation to assist Bicara in prosecuting and maintaining the Biocon Patents under this Section 4.3. Further, within [***] days after the Effective Date, Biocon shall transfer to Bicara or its designee all file wrappers and prosecution histories for the Biocon Patents.
- 4.4 **Discontinuation; Abandonment of Biocon Patents.** If Bicara wishes to discontinue the prosecution of any patent application or to abandon any patent within the Biocon Patents, Bicara shall inform Biocon at least [***] days prior to such discontinuance and Biocon shall, at its option, have the exclusive right to prosecute such patent application or maintain such patent at its expense prior to the date that such discontinuance would otherwise take effect, and such patents shall remain subject to the license granted to Bicara under this License Agreement.
- 4.5 **Prosecution and Maintenance of Arising IP.** Bicara shall have the sole right, but not obligation, to prosecute and maintain any Arising IP in the Territory.
- 4.6 **Intellectual Property Rights Infringements.**
- 4.6.1 If either Party becomes aware of any product or activity of any Third Party that involves or may involve infringement or other violation of any Biocon Patents in the Territory (each, an "**Infringement**"), it shall promptly (but in any event within [***] Business Days of becoming aware of such Infringement) notify the other Party in writing of the infringement or violation.
- 4.6.2 Bicara (or its designee) shall have the first right to bring and control any legal action to enforce Biocon Patents against any Infringement and to defend against any Third Party challenge of the Biocon Patents, at its sole expense as it reasonably determines appropriate. If Bicara or its designee fails to abate such Infringement or to file an action to abate such Infringement and/or fails to defend against such

challenge, within [***] days after a written request from Biocon to do so, or if Bicara discontinues the prosecution of any such action after filing without abating such Infringement, then Biocon shall have the right to enforce and/or defend the Biocon Patents, as applicable, against such Infringement and/or Third Party challenge, as applicable, at its own expense as it reasonably determines appropriate; provided that: (a) [***]; and (b) [***]. Notwithstanding the foregoing, [***] shall continue to defend [***] (the “**Challenged Patent**”) against any Third Party challenge brought prior to the Effective Date, at its own expense, and [***] shall reasonably consult with [***] with respect to such defense and shall not enter into any settlement, without the prior written consent of [***]. At the request of the Party bringing an action related to Infringement in accordance with this Section 4.6.2, the other Party shall provide reasonable assistance in connection therewith, including executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Laws to pursue such action, at each such Party’s sole cost and expense. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery obtained by either or both Biocon and Bicara in connection with or as a result of any Infringement or defense of any Biocon Patent, whether by settlement or otherwise, shall be shared in order as follows: (i) the Party which initiated and prosecuted or defended the action shall recoup all of its costs and expenses incurred in connection with the action; (ii) the other Party shall then, to the extent possible, recover its costs and expenses in connection with the action; and (iii) the portion of any recovery remaining, whether by settlement or judgment, that is allocable to an Infringement or to the defense of Biocon Patent against a Third Party challenge shall be shared between Biocon and Bicara as follows: (x) [***] to the enforcing Party and (y) [***] to the non-enforcing Party.

- 4.6.3 If any Third Party threatens or commences a lawsuit against either Party alleging the Product or Biocon Materials in any way infringes or otherwise violates any intellectual property rights or any other rights of such Third Party in the Territory, that Party shall promptly notify the other Party in writing.

Article 5 Indemnification

- 5.1 **By Bicara.** Bicara shall indemnify, defend, and hold harmless Biocon, its Affiliates, and its and their respective directors, officers, employees, contractors, agents, and assigns (collectively, the “**Biocon Indemnitees**”) against any losses, liabilities, damages, or expenses (including reasonable attorney fees) (individually and collectively, “**Losses**”) arising from any Third Party claim, action, or proceeding to the extent resulting from: (a) [***]; (b) [***]; or (c) [***], except in each case (a)-(c) above, to the extent arising from [***] or [***].
- 5.2 **By Biocon.** Biocon shall indemnify, defend, and hold harmless Bicara, its Affiliates, and its and their respective directors, officers, employees, contractors, agents, and assigns (collectively, the “**Bicara Indemnitees**”) against any Losses arising from any Third Party claim, action, or proceeding to the extent resulting from: (a) [***]; or (b) [***], except in each case (a) and (b), to the extent arising from [***] or [***].

- 5.3 **Procedure.** A Party seeking indemnification pursuant to this Article 5 shall (a) give the indemnifying Party prompt written notice of the applicable Third Party claim, suit, or proceeding (“**Claim**”) (including a copy thereof) served upon it with respect to which such Party intends to claim such indemnification; (b) give the indemnifying Party sole control of the defense and/or settlement thereof; and (c) fully cooperate with the indemnifying Party and its legal representatives in the investigation of any matter the subject of indemnification at the indemnifying Party’s expense. Notwithstanding the foregoing, the indemnifying Party shall have no obligations for any Claim if the indemnified Party makes any admission, settlement or other communication regarding such Claim, without the prior written consent of the indemnifying Party, which consent shall not be unreasonably withheld. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the indemnifying Party.

Article 6 Consideration.

- 6.1 In consideration of the license granted herein by Biocon, pursuant to this Agreement Bicara shall pay Biocon INR fifty-five crore (55 crore), being a fair value determined by an independent valuer.
- 6.2 Any and all liability related to tax (both direct and indirect) including withholding taxes with respect to any payment related to or otherwise in connection with this License Agreement arising in the Territory shall be sole responsibility of Bicara and further, in the event Biocon discharges any such liability, Bicara shall promptly reimburse Biocon.

Article 7 Representation, Warranties and Covenants

- 7.1 Each Party represents, warrants, and covenants to the other as follows:
- 7.1.1 it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation and operations;
- 7.1.2 it has, and will have on all relevant dates, all requisite legal and corporate power to execute and deliver this Agreement, and to carry out and perform its obligations under the terms of this Agreement;
- 7.1.3 the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate corporate action; and
- 7.1.4 such Party audits Affiliates are not, and have not been, debarred or disqualified by any Regulatory Authority.

7.2 Biocon represents, warrants, and covenants to Bicara that:

- 7.2.1 as of the Effective Date, (a) Schedule 1.3 sets forth a complete and accurate list of all contracts entered into by Biocon with its Affiliate or Third Parties that are related to the Product and (b) the Assumed Contracts are in full force and effect and constitute valid and binding obligations of Biocon and, with respect to all other parties, to the knowledge of Biocon, are valid and binding. Neither Biocon nor, to the knowledge of Biocon, the other parties to the Assumed Contracts are in default thereunder, and Biocon has not received or given notice of any default thereunder from or to any of the parties thereto, and there exists no event as of the Effective Date which upon notice or the passage of time, or both, would reasonably be expected to give rise to any default of Biocon or, to the knowledge of Biocon, the other parties thereto. As of the Effective Date, to Biocon's knowledge, there are no liabilities incurred by Biocon under any Assumed Contract or otherwise arising prior to the Effective Date. Biocon has not received written notice, nor does Biocon have any knowledge that any party to any Assumed Contract intends to cancel or terminate any Assumed Contract;
- 7.2.2 as of the Effective Date, Schedule 1.6 sets forth a complete and accurate list of all patents and patent applications Controlled by Biocon or its Affiliates that Cover the Products or the Biocon Material. Biocon and its Affiliates, as applicable, have properly filed, prosecuted and maintained all Biocon Patents, in each case, in accordance with Applicable Laws. The inventions claimed in the Biocon Patents were made solely by the inventor(s) named in the respective Biocon Patents without misappropriation of any trade secrets, confidential information, or other rights of any other person, and no other party has any rights with respect to any such inventions or to the Biocon Patents. All issuance, renewal, maintenance and other payments that are or have become finally due with respect to the Biocon Patents have been timely paid by or on behalf of Biocon;
- 7.2.3 no consent, approval, or authorization of, or registration, notification, declaration or filing to or with, any entity, including any Regulatory Authority or governmental authority, is required to be obtained or made by or with respect to Biocon or its Affiliates in connection with the execution, delivery or performance by Biocon of this Agreement or the consummation of the transactions contemplated hereby, including assignment of the Assumed Contracts to Bicara;
- 7.2.4 it has the right under the Biocon Technology to grant the licenses hereunder to Bicara, and it has not granted any license or other right under the Biocon Technology that is inconsistent with the licenses granted hereunder;
- 7.2.5 there are no claims, judgments, or settlements against Biocon pending, or to Biocon's knowledge, threatened that invalidate or seek to invalidate Biocon Patent except the [***] which is under post grant opposition;
- 7.2.6 there are no pending, or to Biocon's knowledge, threatened adverse actions, suits, or proceedings (including by Regulatory Authorities) against Biocon involving the Assumed Contracts, Biocon Technology or Product;

- 7.2.7 as of the Effective Date, to its knowledge, the Biocon Technology includes all patents and patent applications, Know-How, and Biocon Materials Controlled by Biocon or its Affiliates that is necessary or reasonably useful to develop, manufacture, and commercialize the Products set forth on Schedule 1.18 in the Field as such development, manufacture and commercialization is currently being conducted by Biocon or contemplated to be conducted by Bicara. Biocon has obtained, or caused its Affiliates to obtain, assignments from the inventors of all rights and embodiments in and to the Biocon Technologies;
- 7.2.8 as of the Effective Date, Biocon has complied with all Applicable Laws applicable to the development and manufacture of Products;
- 7.2.9 as of the Effective Date, Biocon owns all right, title and interest in and to the Biocon Technologies and the Product Candidates and the Biocon technologies are free and clear of any liens, pledges, charges, security interests, leases, adverse claims or encumbrances of any kind whatsoever and no Third Party, including any current or former employee or consultant of Biocon and its Affiliates, has any proprietary, commercial or other interest in any of the Biocon Technologies or Product Candidates; and
- 7.2.10 it will use reasonable efforts to update from time to time the list of Biocon Patents and Biocon Materials to set forth any additional Biocon Patents and Biocon Materials of which Biocon becomes aware during the Capture Period.
- 7.3 EXCEPT AS EXPRESSLY GIVEN IN THIS AGREEMENT, NEITHER PARTY MAKES ANY EXPRESS REPRESENTATION OR WARRANTIES AND EACH PARTY HEREBY EXCLUDES AND DISCLAIMS IN THEIR ENTIRETY ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.
- 7.4 Each Party shall perform its obligations and exercise its rights under this license Agreement in compliance with all Applicable Laws, including environmental laws, anti-bribery laws, and regulatory guidelines in the Territory.

Article 8 Limitation of Liability

- 8.1 NOTWITHSTANDING ANYTHING TO THE CONTRARY EXCEPT FOR DAMAGES ARISING FROM ANY BREACH OF CONFIDENTIALITY OBLIGATIONS OR AS MAY BE PAYABLE PURSUANT TO A PARTY'S INDEMNITY OBLIGATIONS, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, INDIRECT DAMAGES, LOSS OF PROFIT, LOSS OF REVENUE, OR LOSS OF USE, EVEN IF INFORMED OF POSSIBILITIES OF SUCH DAMAGES OR LOSSES. EXCEPT FOR DAMAGES ARISING FROM ANY BREACH OF CONFIDENTIALITY OBLIGATIONS OR AS MAY BE PAYABLE PURSUANT TO A PARTY'S INDEMNITY OBLIGATIONS, EACH PARTY'S LIABILITY FOR DIRECT DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT SHALL UNDER NO CIRCUMSTANCE EXCEED [***]. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THESE LIMITATIONS AND EXCLUSIONS APPLY REGARDLESS OF WHETHER LIABILITY ARISES FROM BREACH OF CONTRACT, WARRANTY OR TORT OR UNDER ANY THEORY OF JURISPRUDENCE.

Article 9 Pharmacovigilance and Post Marketing Surveillance

- 9.1 Bicara shall be solely responsible at its expense for complying with any post approval development, or post marketing activities such as any and all routine and non-routine Pharmacovigilance monitoring or studies, and post-marketing surveillance for the Product (including phase 4 clinical trials), including additional clinical trials to obtain, support or maintain Regulatory Approval with respect to the Product. Bicara shall own all data generated pursuant to this Article 9.

Article 10 Confidentiality.

- 10.1 **Permitted Use of Confidential Information.** The Receiving Party shall not use or disclose any Confidential Information, directly or indirectly, for its own benefit, except to exercise its rights or perform its obligations under this Agreement. No other use or disclosure of Confidential Information is permitted except as set forth in this Article 10.
- 10.2 **Non-Disclosure of Confidential Information.** The Receiving Party agrees to protect and maintain the confidentiality of all Confidential Information obtained pursuant to this Agreement. The Receiving Party shall limit access to the Disclosing Party's Confidential Information to the Receiving Party's directors, officers or employees, agents, contractors, licensees, sublicensees and consultants requiring the same on a "need to know" basis, and only then provided that such individuals are bound by a written obligations of non-use and non-disclosure at least as protective of the Confidential Information of Receiving Party as the terms hereof. Subject to Article 2 of this License Agreement, the Receiving Party shall not duplicate, disclose, or discuss any Confidential Information to or with any Third Parties, in whole or in part, without the prior written consent of the Disclosing Party, except the Receiving Party may disclose Confidential Information belonging to the Disclosing Party as follows: (a) to governmental or other regulatory agencies in order to obtain and maintain patent rights consistent with Article 4; (b) disclosure by Bicara or its Affiliate or sublicensee to gain or maintain approval to conduct clinical trials for a Product, to obtain and maintain Marketing Approvals, or to otherwise develop, manufacture, and commercialize Products; (c) disclosure required in connection with any judicial or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders or governmental regulations (or the rules of any recognized stock exchange or quotation system); or (d) disclosure to potential or actual investors or potential or actual acquirers or actual or potential sublicensees in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such potential or actual investor or acquirer or sublicensee agrees to be bound by confidentiality and nonuse obligations consistent with those contained in this Agreement as they apply to the Receiving Party.

- 10.3 **Exceptions to Confidential Information.** Notwithstanding anything to the contrary set forth herein, the Receiving Party shall not be obligated to maintain the confidentiality of any information provided to it under this Agreement which:
- 10.3.1 was at the time of disclosure or subsequently became, through no act, fault or omission of the Receiving Party, available to the general public through publication or otherwise;
 - 10.3.2 was subsequent to the disclosure, lawfully and independently received in good faith by the Receiving Party from a Third Party who was under no duty of confidentiality with respect to such disclosure;
 - 10.3.3 was at the time of disclosure, already known to the Receiving Party without confidentiality obligations, as shown by written records in the possession of or available to the Receiving Party, provided that it was not directly or indirectly derived from the Disclosing Party or its Confidential Information; or
 - 10.3.4 information which the Receiving Party can establish by competent evidence was subsequently and independently developed by employees of or on behalf of the Receiving Party without use of, reference to or access, direct or indirect, of Confidential Information protected by this Agreement.
- 10.4 **Opportunity to Oppose Disclosure.** If the Receiving Party is required by a governmental authority, Regulatory Authority, court of law or administrative order to disclose Confidential Information, then prior to any disclosure, and to the extent permitted by law, the Receiving Party agrees to immediately notify the Disclosing Party and to cooperate with the efforts of Disclosing Party to contest the disclosure, seek an appropriate protective order or other remedy to ensure the continued confidential treatment of such Confidential Information.

Article 11 MISCELLANEOUS

- 11.1 **Assignability.** This Agreement shall not be assigned in whole or in part by any of the Parties to any Third Parties without the prior consent of the other Party; provided, however, that each Party hereto shall be entitled to assign this Agreement without consent of the other Party to: (i) an Affiliate in which event the assigning Party will provide the other Party a written notice of such assignment; or (ii) any successor or Third Party that acquires all or substantially all of the assets to which this Agreement relates by sale, transfer, merger, reorganization, operation of law or otherwise. Any attempted assignment not in accordance with this Section 11.1 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

- 11.2 **Notice.** All notices under this License Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices may be sent by facsimile if confirmed by also sending as described above.

If to Biocon:

Biocon Ltd

20th KM Hosur Road
Electronics City, Bangalore -560 100
India

Attention: Managing Director

Copy to: Head - Legal

If to Bicara:

Bicara Therapeutics Inc.

245 Main Street
Cambridge, MA 02142
United States

Attention: CMO

- 11.3 **No Waiver.** Failure, delay, or any partial exercise by either Party of any right, power, or privilege available to such Party hereunder shall not operate as a waiver or preclude further exercise by such Party of any other right, power, or privilege.
- 11.4 **No License.** Except as set forth in this License Agreement, no right or license, including but not limited to any patent, patent application, trademark, copyright, trade secret or know-how, is granted in the Disclosing Party's Confidential Information to the Receiving Party.
- 11.5 **Descriptive Headings and Interpretation.** All section headings, titles, and subtitles in this Agreement are for convenience of reference only and are to be ignored in any construction of this Agreement's provisions. This Agreement has been prepared on the basis of mutual understanding of the Parties and shall not be strictly construed against either Party as the drafter.
- 11.6 **Governing Law and Dispute Resolution.** This Agreement shall be governed by and shall be construed in accordance with the laws of England and Wales, without reference to conflicts of law principles. The Parties agree that they shall in good faith work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be finally resolved through binding arbitration conducted by International Chamber of Commerce ("ICC") under its International Rules of Arbitration. The arbitration shall be held in London, England and shall be conducted in English by one arbitrator, appointed by both the Parties in accordance with said ICC rules. The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery; provided the arbitrator shall permit such discovery as the arbitrator deems necessary to permit an equitable resolution of the dispute. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or a true copy thereof. The costs of the arbitration, including administrative and arbitrator's fees, shall be shared equally by the Parties, and each Party shall bear its own costs and attorneys' and witnesses' fees incurred in connection with the arbitration. The decision of such arbitrator shall be written, reasoned, final, binding, and conclusive on the Parties, and judgment thereon may be entered in any court having jurisdiction over the Parties and the subject matter hereof. Notwithstanding the foregoing, either Party may apply to any court of competent jurisdiction for injunctive relief or other provisional relief as necessary to protective the rights or interests of such Party.

- 11.7 **Force Majeure.** If either Party is delayed in performing an obligation under this Agreement by strike, lockout, other labor troubles, restrictive governmental or judicial order; riots, insurrection, war, inclement weather, or Acts of God (each, a “Force Majeure”), performance under this Agreement is excused for the period of such delay. The Party affected by such Force Majeure event shall promptly notify the other in writing of the delaying event.
- 11.8 [***].
- 11.9 **Relationship.** The relationship hereby established between the Parties is solely that of independent contractors. This Agreement shall not create any agency, partnership, or joint venture relationship between the Parties.
- 11.10 **No Third Party Beneficiary.** Except as otherwise expressly provided herein, this Agreement shall be for the sole benefit of the Parties to this Agreement and is not intended nor shall be construed to give any person, other than the Parties hereto, any legal or equitable right, remedy or claim.
- 11.11 **Severability.** If any provision of this Agreement is held illegal, unenforceable, or otherwise invalid, such holding shall not affect the other provisions or applications of this Agreement which can be given effect; provided, however, that the Parties shall use their respective best efforts to replace the invalid provision in a manner that conforms as nearly as possible with the original intent of the Parties.
- 11.12 **Complete Understanding.** This Agreement including all schedules and annexures hereto and thereto, and other documents and instruments delivered in connection with the transactions contemplated herewith or therewith, constitutes the complete understanding between the Parties and merges and supersedes all prior discussions, agreements and understandings between the Parties with respect to the subject matter hereof.
- 11.13 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be considered an original and all of which shall constitute one and the same document for all purposes.
- 11.14 **Amendment.** No amendment, modification, supplement, or novation of this Agreement or its Schedules, and no waiver of any of the terms or conditions hereof shall be valid or binding unless made in writing and duly executed by the Parties.

(Signature Page Follows)

IN WITNESS WHEREOF, the Parties hereto have caused this License Agreement to be executed by affixing their signatures below.

Biocon Limited

1. [***] _____
Name: [***]
Title: [***]

2. [***] _____
Name: [***]
Title: [***]

Bicara Therapeutics Inc.

1. [***] _____
Name: [***]
Title: [***]

2. [***] _____
Name: [***]
Title: [***]

Schedule 1.3 (Assumed Contracts)

| <u>Sl. No.</u> | <u>Biocon Entity</u> | <u>Counter Party</u> | <u>Type of Agreement</u> | <u>Start Date</u> | <u>End Date</u> |
|----------------|----------------------|----------------------|--------------------------|-------------------|-----------------|
| 1 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 2 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 3 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 4 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 5 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 6 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 7 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 8 | Biocon Ltd | [***] | [***] | [***] | [***] |
| 9 | Biocon Ltd | [***] | [***] | [***] | [***] |

Schedule 1.5 (Biocon Materials)

[**]

Schedule 1.6 (Biocon Patents)

[**]

Schedule 1.18 (Product)

[**]

CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(B)(10) AND REPLACED WITH [*]. SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

Clinical Trial Collaboration and Supply Agreement

by and among

MSD International GmbH,

MSD International Business GmbH,

and

Collaborator (as defined below)

Clinical Trial Collaboration and Supply Agreement—Information Sheet

| | |
|--|---|
| MSD Agreement Number (LKR Number) | [***] |
| Collaborator Entity Name | Bicara Therapeutics, Inc. |
| Collaborator Address | 245 Main Street, Cambridge, MA 02142 |
| Collaborator Class Compound | Any large molecule that targets both [***] and [***]. |
| Collaborator Compound | BCA-101 |
| Collaborator Clinical Trial | [***] |
| Collaborator JDC Escalation Person Title | [***] |
| Collaborator Notice Block | [***] |
| Effective Date | May 19, 2022 |

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This Clinical Trial Collaboration and Supply Agreement is entered into as of the Effective Date, by and among MSD International GmbH (“**MSDIG**”), MSD International Business GmbH (“**MSDIB**”, and collectively with MSDIG, “**MSD**”), each having a place of business at [***], and Collaborator (as defined below), having a place of business at the Collaborator Address (as defined below). MSD and Collaborator are each referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

- A. MSD holds intellectual property rights to the MSD Compound (as defined below) and is developing the MSD Compound for the treatment of certain tumor types.
- B. Collaborator is developing the Collaborator Compound (as defined below) for the treatment of certain tumor types.
- C. Collaborator desires to sponsor the Collaborator Clinical Trial (as defined below) in which the Collaborator Compound and the MSD Compound would be dosed in Combination (as defined below).
- D. MSD and Collaborator, consistent with the terms of this Agreement, desire to collaborate as described herein, including by providing the MSD Compound and the Collaborator Compound for the MSD Compound Study (as defined below).

NOW, THEREFORE, in consideration of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, agree as follows:

1. **DEFINITIONS.**

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

- 1.1. “**Affiliate**” means, with respect to either Party, a firm, corporation or other entity that, now or hereafter, directly or indirectly owns or controls said Party, or, now or hereafter, is owned or controlled by said Party, or is under common ownership or control with said Party for so long as such control exists. The word “**control**” as used in this definition means: (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity; or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.
- 1.2. “**Agreement**” means this agreement.

- 1.3. “**Alliance Manager**” means the alliance managers appointed by the Parties in accordance with Section 2.3 (Joint Development Committee; Managers).
- 1.4. “**Applicable Law**” means all federal, state, local, national and regional statutes, laws, rules, regulations and directives, and any court order or legally binding administrative order from a governmental authority, in each case, applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including: (i) those promulgated by any Regulatory Authority; (ii) cGMP and GCP; (iii) Data Protection Law; (iv) export control and economic sanctions regulations that prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; (v) anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; (vi) laws and regulations governing payments to healthcare providers; (vii) health, safety and environmental protections; and (viii) the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity on which the securities of a Party or its Affiliates are listed.
- 1.5. “**Business Day**” means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country (or, in the United States, in the state) where the applicable obligations are to be performed are authorized or required by law to be closed.
- 1.6. “**cGMP**” means the Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities as applicable to the Manufacture of the Compounds.
- 1.7. “**Change of Control**” means: (a) the sale of all or substantially all of such Collaborator’s assets or business relating to the Collaborator Compound to a Third Party; or (b) a merger, reorganization or consolidation involving Collaborator in which the voting securities immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) any Third Party (or group of Third Parties acting in concert) becoming the beneficial owner directly or indirectly, of fifty percent (50%) or more of the total voting power of Collaborator.
- 1.8. “**Clinical Quality Agreement**” means an agreement to be entered into by the Parties, or their Affiliates, pursuant to Section 2.4 (Clinical Quality Agreement) to address and govern the quality and handling of clinical drug to be supplied by the Parties for use in the MSD Compound Study.
- 1.9. “**Clinical Data**” means Collaborator Clinical Data, Joint Clinical Data and MSD Clinical Data.

- 1.10. “**Clinical Safety Data**” means all safety and tolerability data from the monotherapy portions of the Collaborator Clinical Trial or other monotherapy clinical trials involving the Collaborator Compound, including all safety reports containing information on adverse events, SAEs, and other information required by any FDA-reporting requirements, including summary tables of laboratory and radiographic data.
- 1.11. “**CMC**” means “**Chemistry Manufacturing and Controls**” as such term of art is used in the pharmaceutical industry.
- 1.12. “**Collaborator**” means the entity specified in the “Collaborator Entity Name” row of the Information Sheet.
- 1.13. “**Collaborator Address**” means the address set forth for Collaborator in the “Collaborator Address” row of the Information Sheet.
- 1.14. “**Collaborator Background Patents**” means any patent Controlled by Collaborator or its Affiliate [***].
- 1.15. “**Collaborator Class Compound**” means the class of compounds set forth in the “Collaborator Class Compound” row of the Information Sheet.
- 1.16. “**Collaborator Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Collaborator Compound Arm(s), if any Collaborator Compound Arm(s) are included in the Collaborator Clinical Trial. Collaborator Clinical Data does not include Sample Testing Results, Joint Clinical Data or MSD Clinical Data.
- 1.17. “**Collaborator Clinical Trial**” means the clinical trial set forth in the “Collaborator Clinical Trial” row of the Information Sheet.
- 1.18. “**Collaborator Compound**” means the compound set forth in the “Collaborator Compound” row of the Information Sheet, excluding, [***].
- 1.19. “**Collaborator Compound Arm(s)**” means any portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound either alone or in concomitant or sequential administration with one or more treatments, but not in Combination with the MSD Compound.
- 1.20. “**Collaborator Escalation Contact**” means the person set forth in the “Collaborator JDC Escalation Person Title” row of the Information Sheet.
- 1.21. “**Collaborator Inventions**” means all Inventions relating to [***].
- 1.22. “**Combination**” means the use or method of using the Collaborator Compound and the MSD [***].

- 1.23. “**Combination Arm(s)**” means the portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound and the MSD Compound in Combination [***].
- 1.24. “**Compounds**” means the Collaborator Compound and the MSD Compound. A “**Compound**” means either the Collaborator Compound or the MSD Compound.
- 1.25. “**Confidential Information**” means any information (including Personal Data (defined in Exhibit C)), Know-How or other proprietary information or materials furnished to a Receiving Party by or on behalf of a Disclosing Party in connection with this Agreement, except to the extent that such information or materials, as demonstrated by competent evidence: (i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through a breach of this Agreement by the Receiving Party; (iv) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (v) was subsequently developed by the Receiving Party without use of the Disclosing Party’s Confidential Information. [***] is deemed the Confidential Information of MSD (and MSD is the “Disclosing Party” and Collaborator the “Receiving Party” with respect to the same). [***] is deemed the Confidential Information of Collaborator [***].
- 1.26. “**Continuing Party**” means the Party continuing prosecution or maintenance pursuant to [Section 10.4](#) (Declining to File, Prosecute or Maintain).
- 1.27. “**Control**” or “**Controlled**” means, with respect to particular information or intellectual property, that the applicable Party or its Affiliate owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense as provided for herein [***].
- 1.28. “**CTA**” means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.
- 1.29. “**Data Protection Law**” has the meaning set forth in EXHIBIT C.
- 1.30. “**Data Protection Terms**” means the terms set forth in [Exhibit C](#) hereto.
- 1.31. “**Data Sharing Schedule**” means the schedule attached hereto as [Schedule I](#).
- 1.32. “**Defending Party**” means a Party controlling the defense of an action pursuant to [Section 14.2.3](#) (Procedure).
- 1.33. “**Delivery**” with respect to the MSD Compound means [***] and, with respect to the Collaborator Compound, [***]. “**Deliver**” shall have a correlative meaning.

- 1.34. “**Disclosing Party**” means a Party (or its Affiliate) disclosing Confidential Information of such Party hereunder [***].
- 1.35. “**Effective Date**” means the date set forth in the “Effective Date” row of the Information Sheet.
- 1.36. “**EMA**” means the European Medicines Agency and any successor agency.
- 1.37. “**Exclusions List**” means: (i) List of Excluded Individuals and Entities on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website including 42 U.S.C. 1320a-7(<https://www.oig.hhs.gov/exclusions/index.asp>); (ii) the U.S. General Services Administrator’s list of Parties Excluded from Programs – System for Award Management (<https://sam.gov/content/exclusions>) and (iii) the debarment list promulgated under 21 U.S.C.335a (<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-appli>)
- 1.38. “**FCPA**” means the U.S. Foreign Corrupt Practices Act.
- 1.39. “**FDA**” means the United States Food and Drug Administration.
- 1.40. “**GCP**” means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use that may be in effect from time to time and applicable to the testing of the Compounds.
- 1.41. “**Government Official**” means: (i) any officer or employee of a government or any department, agency or instrument of a government; (ii) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (iii) any officer or employee of a company or business owned in whole or part by a government; (iv) any officer or employee of a public international organization such as the World Bank or United Nations; (v) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; or (vi) any candidate for political office; who, in each of the foregoing cases (i) through (v), when such Government Official is acting in an official capacity or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either Party.
- 1.42. “**IND**” means any Investigational New Drug Application as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an “Investigational Medicinal Product Dossier” in the European Union.

- 1.43. “**Information Sheet**” means the table entitled Information Sheet set forth just before the preamble to this Agreement.
- 1.44. “**Inventions**” means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together: [***].
- 1.45. “**Joint Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Combination Arm(s); provided however, that Joint Clinical Data does not include [***].
- 1.46. “**Joint Development Committee**” or “**JDC**” means the committee to be established by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).
- 1.47. “**Joint Patent Application**” means a Patent Application filed in respect to any Joint Invention.
- 1.48. “**Joint Patent**” means a Patent that issues from a Joint Patent Application.
- 1.49. “**Joint Invention**” means any [***].
- 1.50. “**Kit**” means a single vial of MSD Compound, as detailed in the pro-forma invoice that accompanied the MSD Compound for which MSD is entitled to reimbursement pursuant to Sections 6.10 (Manufacturing Costs) or 8.9.2 (Non-Conformance).
- 1.51. “**Know-How**” means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.
- 1.52. “**Liability**” means any loss, damage, reasonable costs and expenses (including reasonable attorneys’ fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out [***].
- 1.53. “**Manufacture**,” “**Manufactured**,” or “**Manufacturing**” means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply.
- 1.54. “**Manufacturer’s Release**” or “**Release**” has the meaning ascribed to release of the MSD Compound in the Clinical Quality Agreement.

- 1.55. “**Manufacturing Site**” means the facilities where a Compound is Manufactured by or on behalf of a Party.
- 1.56. “**MSD**” has the meaning set forth in the preamble.
- 1.57. “**MSD Background Patents**” means any patent Controlled by MSD or its Affiliate that: [***].
- 1.58. “**MSD Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the MSD Compound Arm(s), if any MSD Compound Arm(s) are included in the Collaborator Clinical Trial; provided however, that MSD Clinical Data does not include [***].
- 1.59. “**MSD Compound**” means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody [***].
- 1.60. “**MSD Compound Arm(s)**” means any portion of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments but not in Combination with the Collaborator Compound.
- 1.61. “**MSD Compound Study**” means the arms of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments (including the Collaborator Compound). The MSD Compound Study includes the Combination Arm(s) and any MSD Compound Arm(s) included in the Collaborator Clinical Trial.
- 1.62. “**MSD Inventions**” means all Inventions relating to or covering [***], and not related to or covering [***], and any improvements related thereto, regardless of whether such Invention or improvement was invented solely by MSD or Collaborator or jointly by the Parties.
- 1.63. “**NDA**” means a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in a country or group of countries.
- 1.64. “**Non-Conformance**” means, with respect to a given unit of Compound: (i) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound; or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Article 8 (Supply and Use of Compounds) or Section 13.2 (Compounds). “**Non-Conforming**” shall have a correlative meaning.

- 1.65. “**Non-Proceeding Party**” means a Party that does not wish to proceed with the Subsequent Study in accordance with Section 2.9.2 (Subsequent Study).
- 1.66. “**Non-Pursuing Party**” means a Party not pursuing the filing, prosecution or maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.67. “**Opting-out Party**” means a Party that wishes to discontinue the prosecution and maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.68. “**Other Party**” means a Party not controlling the defense of an action pursuant to Section 14.2.3 (Procedure).
- 1.69. “**Parties**” and “**Party**” have the meanings set forth in the preamble.
- 1.70. “**Patent**” means a patent, extension, registration, supplementary protection certificate or the like that issues from a given Patent Application.
- 1.71. “**Patent Application**” means a patent application (including any provisional, substitution, divisional, continuation, continuation-in-part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of a given Invention.
- 1.72. “[***] **Antagonist**” means any [***].
- 1.73. “**Person**” means any entity, including any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, or governmental entity.
- 1.74. “**Pharmacovigilance Agreement**” means the pharmacovigilance agreement to be executed by the Parties, or their Affiliates, pursuant to Section 2.6 (Pharmacovigilance Agreement).
- 1.75. “**Project Manager**” means the Project Managers to be designated by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).
- 1.76. “**Protocol**” means the written documentation that describes the Collaborator Clinical Trial and sets forth specific activities to be performed as part of the conduct of the Collaborator Clinical Trial.

- 1.77. **“Proceeding Party”** means a Party that wishes to proceed with the Subsequent Study pursuant to Section 2.9.2 (Subsequent Study).
- 1.78. **“Pursuing Party”** means a Party pursuing the filing, prosecution or maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.79. **“Receiving Party”** means a Party (or its Affiliate) receiving Confidential Information of the other Party hereunder or on whose behalf such Confidential Information is received hereunder.
- 1.80. **“Regulatory Approvals”** means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from any Regulatory Authority or other competent authority for the development, registration, importation and distribution of such Compound in any jurisdiction for use in the MSD Compound Study.
- 1.81. **“Regulatory Authorities”** means the FDA, national regulatory authorities, the EMA, any successor agency to the FDA or EMA and any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction.
- 1.82. **“Regulatory Documentation”** means all submissions to Regulatory Authorities in connection with the development of a Compound, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse-event files, complaint files, inspection reports and Manufacturing records, in each case together with all supporting documents (including any documents that include Clinical Data).
- 1.83. **“Related Agreements”** means the Pharmacovigilance Agreement and the Clinical Quality Agreement.
- 1.84. **“Related Entities”** means, with respect to each of Collaborator and MSD, such Party’s Affiliates and its and their directors, officers, employees and others acting on its or their behalf.
- 1.85. **“Right of Reference”** means the “right of reference” defined in 21 CFR 314.3(ii) including, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information and data (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation filed with such Regulatory Authority with respect to a Party’s Compound.
- 1.86. **“SAE”** means a serious adverse event.
- 1.87. **“Samples”** means biological specimens collected from subjects participating in the MSD Compound Study, including any urine, blood and tissue samples.

- 1.88. “**Sample Testing**” means the analyses to be performed by each Party using the applicable Samples, as described in the Sample Testing Schedule.
- 1.89. “**Sample Testing Results**” means the data and results arising from the Sample Testing.
- 1.90. “**Sample Testing Schedule**” means the schedule attached hereto as Schedule II.
- 1.91. “**Sensitive Information**” means [***] Confidential Information relating to MSD Inventions, the MSD Compound or the Combination.
- 1.92. “**Specifications**” means the requirements to which a Compound must conform. The Specifications for a Compound will be set forth in the certificate of analysis accompanying each batch of Compound supplied for use in the MSD Compound Study.
- 1.93. “**Study Completion**” means: (i) the date when [***]; or (ii) an alternative date as agreed to by the JDC.
- 1.94. “**Subcontractors**” means any and all Third Parties to whom a Party delegates any of its obligations hereunder.
- 1.95. “**Subsequent Study**” means a [***] study for [***].
- 1.96. “**Sunshine Act**” shall mean the Physician Payments Sunshine Act as amended from time to time.
- 1.97. “**Term**” means the term of this Agreement as described under Section 6.1 (Term).
- 1.98. “**Third Party**” means any Person or entity other than Collaborator, MSD or their respective Affiliates.
- 1.99. “**Third-Party Infringement**” means [***].
- 1.100. “**Toxicity and Safety Data**” means all clinical adverse-event information or patient-related safety data [***].
- 1.101. “**Transparency Report**” means a transparency report in connection with reporting payments and other transfers of value made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and a Party’s applicable policies.
- 1.102. “**VAT**” means a value-added or similar tax.
- 1.103. “**Violation**” means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (i) convicted of any of the felonies identified among the Exclusion Lists or (ii) identified or listed as having an active exclusion on any Exclusion List; or (iii) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under any Exclusion List.

2. **PERFORMANCE OF THE AGREEMENT, RELATED AGREEMENTS.**

- 2.1. The Collaborator Clinical Trial. Collaborator is conducting or intends to conduct the Collaborator Clinical Trial, which Collaborator Clinical Trial has or is intended to have a Combination Arm(s). In addition, the Collaborator Clinical Trial may (or may not) have a Collaborator Compound Arm(s), an MSD Compound Arm(s), or both. The term “Collaborator Clinical Trial” as used in this Agreement refers to [***]. The term “MSD Compound Study” refers to [***]. Collaborator Clinical Trial, Collaborator Compound Arm(s), Combination Arm(s), MSD Compound Arm(s) and MSD Compound Study all refer to such arms as are intended to be conducted in accordance with the Protocol, including the Protocol as may be amended in accordance with Article 4 (PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS).
- 2.2. Generally. Each Party shall: (i) contribute such resources as are necessary to conduct the activities contemplated by this Agreement; and (ii) act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.
- 2.3. Joint Development Committee; Managers.
- 2.3.1. The Parties shall form the Joint Development Committee made up of an equal number of representatives of MSD and Collaborator, which shall have responsibility for coordinating [***]. The JDC will review and finalize the Protocol in accordance with Section 4.1 (Protocol). Each Party shall designate a Project Manager who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties with respect to the MSD Compound Study and shall be entitled to attend meetings of the JDC. JDC members will be agreed by both Parties.
- 2.3.2. The JDC shall meet [***] to provide an update on the progress of the MSD Compound Study. The JDC may meet in person or by means of teleconference, internet conference, videoconference or similar means. Prior to any such meeting, Collaborator’s Project Manager shall provide a written update to MSD’s Project Manager and Alliance Manager containing information about the overall progress of the MSD Compound Study, recruitment status, interim analysis (if available), final analysis and other information relevant to the conduct of the MSD Compound Study (and data relating to the Collaborator Clinical Trial reasonably requested by MSD and relevant to the MSD Compound Study).

- 2.3.3. In addition to a Project Manager, each Party shall designate an Alliance Manager who shall serve as the primary point of contact for any issues arising under this Agreement and shall endeavor to ensure clear and responsive communication and the effective exchange of information between the Parties. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree. In the event that an issue arises and the Alliance Managers do not, after good faith efforts, reach agreement on such issue, or if there is a decision to be made by the JDC on which the members of the JDC do not unanimously agree, the issue shall be elevated to the Senior Vice President of Clinical Research for MSD and the Collaborator Escalation Contact. In the event such escalation does not result in resolution or consensus: (i) [***] shall have final decision-making authority with respect to issues related to [***]; and (ii) [***] shall have final decision-making authority with respect to issues related to [***] and [***].
- 2.4. Clinical Quality Agreement. The Parties will execute the Clinical Quality Agreement prior to any supply of MSD Compound hereunder, and no later than [***] days after the Effective Date. The Clinical Quality Agreement shall, among other things: [***]. Quality matters and the Manufacture of the MSD Compound shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.
- 2.5. Data Protection. The Parties will comply with the Data Protection Terms set forth on Exhibit C [***].
- 2.6. Pharmacovigilance Agreement. The Parties will execute the Pharmacovigilance Agreement prior to MSD Delivering MSD Compound to Collaborator hereunder. The Pharmacovigilance Agreement will: (i) include safety data exchange procedures; (ii) facilitate appropriate safety reviews; (iii) govern the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the MSD Compound and Collaborator Compound in the MSD Compound Study; and (iv) shall enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities, all of the foregoing in accordance with Applicable Law. For the avoidance of doubt, the obligations to provide safety data under the Pharmacovigilance Agreement will be independent of any obligations to provide safety data pursuant to this Agreement.

- 2.7. Delegation of Obligations. Each Party shall have the right to delegate any portion of its obligations hereunder [***] upon the other Party's prior consent. Notwithstanding any delegation of its obligations hereunder, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by its Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.
- 2.8. Relationship. Without prejudice to Section 2.9 (Subsequent Study), this Agreement does not create any obligation for either Party to provide any compound other than its Compound or to provide its Compound for any activities other than the MSD Compound Study. Except as expressly set forth in Section 2.9 (Subsequent Study), nothing in this Agreement shall: [***]. Each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, [***]. Notwithstanding the foregoing, and notwithstanding any implication to the contrary in this Agreement, [***]. Collaborator and MSD have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Collaborator Clinical Trial. Except as expressly set forth in Section 2.9 (Subsequent Study), nothing in this Agreement obligates the Parties to enter into any agreement other than the Related Agreements now or in the future.
- 2.9. [***]
- 2.9.1. [***]
- 2.9.2. [***]

3. CONDUCT OF THE MSD COMPOUND STUDY.

- 3.1. Sponsor. Collaborator shall act as the sponsor of the Collaborator Clinical Trial under its own IND for the Collaborator Compound with a Right of Reference to the IND of the MSD Compound as described in Section 3.5 (Regulatory Matters); provided, however, that in no event shall Collaborator file an additional IND for the MSD Compound Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests such an additional IND for the MSD Compound Study, the Parties shall meet and agree on an approach to address such requirement.
- 3.2. Clinical Safety Data Review. Prior to dosing any patient with the MSD Compound in the Combination Arm(s), Collaborator shall invite MSD to attend a safety review meeting, during reasonable business hours, to review the most recent Clinical Safety Data (and other data reasonably requested by MSD to evaluate the safety of the proposed Combination Arm(s)). Collaborator shall provide MSD with reasonable advance notice of such meeting. [***].

- 3.3. Performance. Collaborator shall ensure that the MSD Compound Study and all related activities are performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.
- 3.4. Debarred Personnel; Exclusions Lists. [***].
- 3.5. Regulatory Matters. Collaborator shall: (i) obtain all Regulatory Approvals from all Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the MSD Compound Study prior to its initiation; and (ii) follow all directions from any such Regulatory Authorities, ethics committees and institutional review boards. MSD shall have the right (but not the obligation) to participate in any discussions (including meetings) with a Regulatory Authority regarding matters related to the MSD Compound Study or the MSD Compound and to collaborate on questions posed to Regulatory Authorities regarding design and conduct of the MSD Compound Study. [***].
- 3.6. Documentation. Collaborator shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Collaborator shall provide to MSD all (a) MSD Compound Study information and documentation; and (b) any other Collaborator Clinical Trial information and documentation reasonably requested by MSD to enable MSD to: (i) comply with any of its legal, regulatory or contractual obligations, or any request by any Regulatory Authority, related to the MSD Compound; and (ii) determine whether the MSD Compound Study has been performed in accordance with this Agreement [***].
- 3.7. Copies. Collaborator shall provide to MSD copies of all Joint Clinical Data and any MSD Clinical Data in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing Schedule or mutually agreed; provided, however, that a complete copy of the Joint Clinical Data and any MSD Clinical Data shall be provided to MSD no later than [***] days following MSD Compound Study Completion or any sooner termination of this Agreement. Collaborator shall ensure that: (i) all patient authorizations and consents required under Applicable Law in connection with the Collaborator Clinical Trial permit such sharing of Joint Clinical Data and any MSD Clinical Data with MSD; and (ii) it complies with Applicable Law in transferring personal data hereunder.

- 3.8. Sample Testing.
- 3.8.1. Collaborator shall provide Samples to MSD as specified in the Protocol and as agreed to by the Joint Development Committee. Each Party shall use the Samples only for Sample Testing in accordance with the Sample Testing Schedule, all Applicable Law and the Protocol. [***].
- 3.8.2. [***].
- 3.9. Ownership and Use of Joint Clinical Data.
- 3.9.1. [***]. Collaborator shall maintain the Joint Clinical Data and any MSD Clinical Data in its internal database; [***].
- 3.9.2. [***].
- 3.9.3. Notwithstanding the foregoing, [***].
- 3.9.4. Notwithstanding anything to the contrary in this Agreement, including this Section 3.9 (Ownership and Use of Joint Clinical Data), Collaborator may: [***].
- 3.10. Regulatory Submission. It is understood and acknowledged by the Parties that positive Clinical Data may be used to [***].
- 3.11. Certain Memoranda and Reports. Promptly following MSD Compound Study Completion, Collaborator shall provide to MSD an electronic draft of the top-line results memorandum and an electronic draft of the final report of the results of the MSD Compound Study. MSD shall have [***] days after receipt of such results memorandum and [***] days after receipt of such final report to provide comments thereon. Collaborator shall consider any comments provided by MSD on either document and shall not include any statements in either document relating to [***]. Collaborator shall deliver to MSD a final version of each such document promptly following finalization thereof.
- 3.12. Licensing.
- 3.12.1. Nothing in this Agreement shall prohibit or restrict a Party from licensing, assigning or transferring to an Affiliate or Third Party such Party's Compound [***] owned solely by such Party.
- 3.12.2. A Party may license, assign or transfer to an Affiliate or Third Party, subject to any obligations or restrictions set forth in this Agreement, such Party's interest in the [***] solely to the extent such licensee, assignee or transferee agrees in writing to be bound by the terms of this Agreement with respect to [***].

4. **PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS.**

- 4.1. *Protocol.* A synopsis of the agreed initial Protocol and any agreed draft statistical analysis plan for the MSD Compound Study or Collaborator Clinical Trial are attached hereto as Exhibit A. Collaborator shall: [***]. To the extent the Parties, acting through the JDC or otherwise through their applicable representatives, cannot agree unanimously regarding the contents of the Protocol for final approval: [***]. Notwithstanding anything to the contrary contained herein, each Party, in its sole discretion, shall have the sole right to determine [***] and shall have the final decision on all matters relating to [***].
- 4.2. *Informed Consent.* Collaborator shall prepare the patient informed-consent form for the MSD Compound Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with MSD (it being understood and agreed that the portion of the informed-consent form relating to the Sample Testing of the MSD Compound shall be provided to Collaborator by MSD and adopted by Collaborator).
- 4.3. *Changes to Protocol or Informed Consent.* Any proposed changes to: [***].
- 4.4. *Transparency Reporting.* Collaborator is solely responsible for reporting payments and other transfers of value, (including supply of MSD Compound), made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and Collaborator's applicable policies. Promptly after the Effective Date, Collaborator will notify MSD of Collaborator's point of contact for purposes of receiving information from MSD pursuant to this Section 4.4, along with such contact's full name, email address, and telephone number. Collaborator may update such contact from time to time by notifying MSD pursuant to Article 22 (NOTICES). Where applicable, MSD will provide to such Collaborator contact all information regarding the value of the MSD Compound provided for use in the MSD Compound Study as required for such reporting. In the event that the value of the MSD Compound provided pursuant to this Section 4.4 materially changes, MSD shall notify Collaborator of such revised value and the effective date thereof.
- 4.4.1. **Periods Collaborator is Not Required to Report.** With respect to any annual reporting period in which [***] Collaborator will:
(i) notify MSD within [***] days after the commencement of such reporting period that Collaborator is not so required; and (ii) during such reporting period Collaborator will track and provide to MSD data regarding "indirect" payments or other transfers of value by Collaborator to health care professionals to the extent such payments or other transfers of value were

required, instructed, directed or otherwise caused by MSD pursuant to this Agreement in the format requested by MSD and provided on a basis to be agreed upon by both Parties. Collaborator represents and warrants that any data provided by Collaborator to MSD pursuant to this [Section 4.4](#) will be complete and accurate to the best of Collaborator's knowledge.

4.5. *Financial Disclosure*. To the extent required by Applicable Law, Collaborator will [***].

5. **ADVERSE EVENT REPORTING.**

5.1. *Pharmacovigilance*. Collaborator will be solely responsible for safety reporting for the Collaborator Clinical Trial and related activities, all in accordance with Applicable Law.

5.2. *Transmission of SAEs*. Collaborator will transmit to MSD all SAEs from the MSD Compound Study as set forth below. All cases will be transmitted on a CIOMS-1 form in English.

5.2.1. For fatal and life-threatening SAEs, Collaborator will transmit a processed case within [***] calendar days after receipt by Collaborator of notice of such SAEs.

5.2.2. For all other SAEs and newly diagnosed cancer, Collaborator will transmit a processed case within [***] calendar days after receipt by Collaborator of notice of such SAEs.

5.2.3. Cases of disease progression will be handled as outlined in the Protocol, and if the Protocol specifies that such cases are collected as SAEs, Collaborator will transmit such cases to MSD within the applicable timeframe set forth in [Section 5.2.1](#) or [Section 5.2.2](#).

5.2.4. For all other reportable information that includes: (i) overdose, exposure during pregnancy or lactation; and (ii) cases of potential drug-induced liver injury where the patient was exposed to the MSD Compound (if required to be collected or identified per the Protocol), Collaborator will transmit a processed case within [***] calendar days after receipt by Collaborator of such information.

6. **TERM AND TERMINATION.**

6.1. *Term*. The Term shall commence on the Effective Date and shall continue in full force and effect until delivery of final documents by Collaborator pursuant to [Section 3.11](#) (Certain Memoranda and Reports), unless terminated earlier by either Party pursuant to this [Article 6](#).

6.2. *MSD Termination for Unsafe Use*. In the event MSD notifies Collaborator that it in good faith believes that the MSD Compound is being used unsafely in the MSD Compound Study and the grounds for such belief, and if either MSD believes such matter is not reasonably capable of remedy or if Collaborator fails to promptly remedy such issue to MSD's reasonable satisfaction, MSD may terminate this Agreement and the supply of the MSD Compound by notice to Collaborator with immediate effect.

- 6.3. Termination for Breach. Either Party may terminate this Agreement by notice with immediate effect if the other Party commits a material breach of this Agreement and such material breach continues for [***] days after receipt of notice thereof from the non-breaching Party; provided that within [***] days after receipt of such notice the breaching Party has taken reasonable steps to address and initiate measures to cure such breach; provided further that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement by notice effective at the expiration of such [***]-day cure period. Either Party shall have the right to terminate this Agreement by notice to the other Party with immediate effect if such other Party fails to perform any of its obligations under Section 13.4 (Anti-Corruption) or breaches any representation or warranty contained in Section 13.4 (Anti-Corruption). In addition: (i) this Agreement may be terminated by the non-breaching Party for material breach of any other Clinical Trial Collaboration and Supply Agreement between the Parties (or their Affiliates) involving MSD Compound if such material breach occurred or was discovered during the Term and such material breach is not cured in accordance with the terms of such other Clinical Trial Collaboration and Supply Agreement; and (ii) in the event this Agreement is terminated pursuant to this Section 6.3, the terminating Party will have the right to terminate any or all other Clinical Trial Collaboration and Supply Agreements between the Parties by written notice given within [***] days after termination of this Agreement becomes effective pursuant to this Section 6.3.
- 6.4. Termination for Patient Safety. If either Party determines in good faith that the MSD Compound Study or Collaborator Clinical Trial may unreasonably adversely affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the MSD Compound Study or Collaborator Clinical Trial to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the proposed modifications and may instead terminate this Agreement immediately by notice to the other Party with immediate effect. Furthermore, the notifying Party may terminate this Agreement by notice to the other Party with immediate effect if, in its sole discretion, it believes that the modifications proposed by the other Party will not resolve the patient safety issue.

- 6.5. Termination for Regulatory Action; Force Majeure; Other Reasons. (i) Either Party may terminate this Agreement by notice to the other Party with immediate effect in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the MSD Compound Study. (ii) [***]. (iii) Additionally, either Party shall have the right to terminate this Agreement by notice with immediate effect to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound for medical, scientific or legal reasons.
- 6.6. Return of MSD Compound. If Collaborator remains in possession (including through any Affiliate or Subcontractor) of MSD Compound at the time this Agreement expires or is terminated, Collaborator shall promptly return or destroy all unused MSD Compound as instructed by MSD in its sole discretion. Collaborator shall provide certification of any requested destruction.
- 6.7. Survival. The provisions of [***] shall survive the expiration or termination of this Agreement.
- 6.8. No Prejudice. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party for any breach of this Agreement. Except as set forth in [Section 6.10](#) (Manufacturing Costs) and the foregoing sentence, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement.
- 6.9. Confidential Information. Upon expiration or termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions) furnished to the Receiving Party; provided, however that the Receiving Party may retain one copy of such Confidential Information in its confidential files, solely for purposes of exercising the Receiving Party's rights hereunder, satisfying its obligations hereunder or complying with any legal proceeding or requirement with respect thereto, and provided further that the Receiving Party shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information so long as such electronic files are: (i) maintained only on centralized storage servers (and not on personal computers or devices); (ii) not accessible by any of its personnel (other than its information technology specialists); and (iii) not otherwise accessed subsequently except with the written consent of the Disclosing Party or as required by law or legal process. Such retained copies of Confidential Information shall remain subject to the confidentiality and non-use obligations herein.

- 6.10. *Manufacturing Costs*. In the event of termination by MSD pursuant to Section 6.2 (MSD Termination for Unsafe Use) or 6.3 (Termination for Breach), [***].
7. **COSTS.**
- Each Party will be responsible for its own internal costs and expenses to support the Collaborator Clinical Trial, including: [***].
8. **SUPPLY AND USE OF COMPOUNDS.**
- 8.1. *Supply of the Compounds*. Subject to the terms and conditions of this Agreement, each of Collaborator and MSD will use commercially-reasonable efforts to supply, or cause to be supplied, its Compound in the quantities and on the timelines set forth in Exhibit B, for use in the MSD Compound Study. If a change to the Protocol in accordance with Article 4 (PROTOCOL AND INFORMED CONSENTS; CERTAIN COVENANTS) requires an increase of the quantity of MSD Compound to be provided of more than [***], the Parties shall amend Exhibit B to reflect such changes. Each Party shall also provide the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, if a Party is: (i) not supplying its Compound in accordance with the terms of this Agreement, then the other Party shall have no obligation to supply its Compound; or (ii) allocating under Section 8.10 (Shortage; Allocation), then the other Party may allocate proportionally.
- 8.2. *Manufacturing Delay*. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound hereunder.
- 8.3. *Compound Commitments*. Each Party agrees, at its own cost, to Manufacture and supply its Compound in accordance with this Agreement and the Related Agreements. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that Collaborator shall be responsible for obtaining Regulatory Approvals for the MSD Compound Study as set forth in Section 3.5 (Regulatory Matters)).
- 8.4. *Minimum Shelf Life Requirements*. Each Party shall use commercially-reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the MSD Compound Study requirements.

8.5. Provision of Compounds.

- 8.5.1. MSD will Deliver the MSD Compound to the location specified by Collaborator. Title for the MSD Compound shall transfer from MSD to Collaborator [***]. All costs associated with the subsequent transportation, warehousing and distribution of MSD Compound shall be borne by Collaborator. Collaborator will, or will cause its designee to: (i) take Delivery of the MSD Compound supplied hereunder; (ii) perform the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement; (iii) subsequently label and package the MSD Compound (in accordance with Section 8.6 (Labeling and Packaging; Use, Handling and Storage)); and promptly ship the MSD Compound to the MSD Compound Study sites for use in the MSD Compound Study, in compliance with Applicable Law and the Clinical Quality Agreement; (iv) keep complete and accurate records pertaining to the use and disposition of MSD Compound, including records relating to its storage, shipping (cold chain), in-transport temperature recorder(s), receipt verification, chain-of-custody activities and usage and inventory reconciliation; (v) make the records described in subsection (iv) and such other documentation as may be reasonably requested by MSD available for review by MSD for the purpose of conducting investigations for the determination of MSD Compound safety or efficacy and Collaborator's compliance with this Agreement with respect to the MSD Compound.
- 8.5.2. Collaborator is solely responsible for supplying (including all Manufacturing, acceptance and release testing) the Collaborator Compound for the Collaborator Clinical Trial and the subsequent handling, storage, transportation, warehousing and distribution of all such Collaborator Compound. Collaborator shall ensure that all such activities are conducted in compliance with Applicable Law and, with respect to the MSD Compound Study, the Clinical Quality Agreement.

8.6. Labeling and Packaging; Use, Handling and Storage.

- 8.6.1. The Parties' obligations with respect to the labeling and packaging of the MSD Compound are as set forth in the Clinical Quality Agreement. MSD shall provide the MSD Compound to Collaborator in the form of [***].
- 8.6.2. Collaborator shall: (i) use the MSD Compound solely for purposes of performing the MSD Compound Study; and (ii) not use the MSD Compound in any manner that is inconsistent with this Agreement or for any commercial purpose. Collaborator shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the MSD Compound, and in particular shall not analyze the MSD Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.

- 8.7. Product Specifications. A certificate of analysis shall accompany each shipment of the MSD Compound to Collaborator. Upon request, Collaborator shall provide MSD with a copy of a certificate of analysis covering each shipment of Collaborator Compound used in the MSD Compound Study.

- 8.8. Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site, provided that such changes shall be in accordance with the Clinical Quality Agreement.
- 8.9. Product Testing: Nonconformance.
- 8.9.1. **After Manufacturer's Release**. After Manufacturer's Release of the MSD Compound and concurrently with Delivery of the Compound to Collaborator, MSD shall provide Collaborator with the documentation described in the Clinical Quality Agreement. Collaborator shall conduct the acceptance procedures under the Clinical Quality Agreement within the time frames set forth therein. Collaborator shall be solely responsible for taking all steps necessary to determine that MSD Compound or Collaborator Compound, as applicable, is suitable for release before making such Compounds available for human use, and MSD shall assist Collaborator as Collaborator reasonably requests in making such determination for the MSD Compound. Collaborator shall be responsible for storage and maintenance of the MSD Compound until it is tested and released, which storage and maintenance shall be in compliance with: (i) the Specifications for the MSD Compound, (ii) the Clinical Quality Agreement, (iii) Applicable Law, and (iv) any specific storage and maintenance requirements as may be provided by MSD from time to time. Collaborator shall be responsible for any failure of the MSD Compound to meet the Specifications to the extent caused after Delivery to Collaborator hereunder [***].
- 8.9.2. **Non-Conformance**.
- 8.9.2.1. In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.9.1 (After Manufacturer's Release)), such Party shall immediately notify the other Party. Notification related to MSD Compound shall be in accordance with the Clinical Quality Agreement. MSD shall investigate any Non-Conformance of the MSD Compound in accordance with the Clinical Quality Agreement.
- 8.9.2.2. In the event that all or any portion of any proposed or actual shipment of the MSD Compound is agreed to be Non-Conforming at the time of Delivery to Collaborator then MSD shall replace any such Non-Conforming MSD Compound that has not been administered. [***]. In the event MSD Compound is lost or damaged by Collaborator after Delivery, MSD shall [***]. Except as set forth in this Section 8.9.2.2, MSD shall have no obligation replace any MSD Compound supplied hereunder.

8.9.2.3. Collaborator shall be responsible for, and MSD shall have no obligation or liability with respect to, any Collaborator Compound that is found to have a Non-Conformance. Collaborator shall promptly replace any such Collaborator Compound that has not been administered. The sole and exclusive remedies of MSD with respect to any Collaborator Compound that is found to have a Non-Conformance at the time of Delivery shall be [***].

8.9.3. **Resolution of Discrepancies.** Disagreements regarding any determination of Non-Conformance by Collaborator shall be resolved in accordance with this Clinical Quality Agreement or, in situations where the Clinical Quality Agreement does not apply, Section 21 (GOVERNING LAW; DISPUTE RESOLUTION) of this Agreement.

- 8.10. Shortage; Allocation. If a Party believes in good faith that it will not be able to fulfill its supply obligations hereunder because its Compound is in short supply, such Party will provide prompt written notice to the other Party of such shortage, the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply and the Parties will promptly discuss the situation (including allocation of Compound supplied hereunder within the MSD Compound Study). The Party experiencing the shortage shall have sole discretion, subject to Applicable Law, to determine how much Compound it will supply during the shortage, and such Party shall not be deemed to be in breach of this Agreement for failure to supply any quantities of its Compound as a result of such shortage. In case of one Party's shortage of its Compound, the other Party shall be relieved of its obligations under this Agreement to the extent impacted by such shortage.
- 8.11. Quality Control. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality-assurance and quality-control procedures as are required by the Specifications, cGMPs and (with respect only to the MSD Compound) the Clinical Quality Agreement.
- 8.12. VAT. Where MSD is treated as making a supply of goods in a particular jurisdiction for no consideration for VAT purposes, and Collaborator is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, Collaborator shall be obliged to pay to MSD the amount of VAT properly chargeable on such supply. Collaborator shall pay such VAT to MSD on receipt of a valid VAT invoice from MSD issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable. MSD will: (i) determine, in

accordance with Applicable Law, the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable; and (ii) provide Collaborator any information or copies of documents in MSD's Control as are reasonably necessary for VAT purposes to evidence that such supply will take, or has taken, place in the same jurisdiction.

9. **CONFIDENTIALITY.**

9.1. Confidential Information. Subject to Section 13.4.8, Collaborator and MSD agree to hold in confidence all Confidential Information of the other Party and use such Confidential Information only to fulfill its obligations or exercise its rights hereunder or under the Related Agreements. Without limiting the foregoing, the Receiving Party may not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent such disclosure is: (i) required by Applicable Law; (ii) pursuant to the terms of this Agreement or the Related Agreements; or (iii) necessary for the conduct of the MSD Compound Study, and in each case (i) through (iii) provided that the Receiving Party shall provide reasonable advance notice to the Disclosing Party before making such disclosure.

9.2. Required Disclosures. Notwithstanding anything herein to the contrary, including Section 9.1.1, Section 9.5, and Section 12.3, if a Receiving Party is required to disclose any Confidential Information, including the existence or terms of this Agreement, pursuant to Applicable Law, such Party shall promptly inform the other Party of the disclosure that is being sought, and consult and cooperate fully with the other Party in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Without limiting the foregoing, any proposed press release or other public announcement concerning this Agreement that is required by Applicable Law shall be provided to the other Party for review and comment no less than [***] Business Days prior to the proposed date of publication or announcement. The Party seeking disclosure shall endeavor in good faith to secure confidential treatment of all Confidential Information, including the existence or terms of this Agreement, or reasonably assist the other Party in seeking a protective order or other confidential treatment. All such information so disclosed shall remain otherwise subject to the confidentiality and non-use provisions of this Article 9.

9.3. [***].

9.4. Confidentiality of Inventions. Notwithstanding the foregoing: [***] such Party shall have the right to use and disclose such Confidential Information [***], subject to compliance with the express terms of Articles 10 (INTELLECTUAL PROPERTY), 11 (REPRINTS; RIGHTS OF CROSS-REFERENCE) and 12 (PUBLICATIONS; PRESS RELEASES).

- 9.5. Personal Identifiable Data. All Confidential Information containing personal identifiable data or Personal Data shall be handled in accordance with all applicable data-protection and privacy laws, rules and regulations [***].
- 9.6. Publicity/Use of Names. Except as set forth in Section 12.3 (Press Releases), [***] no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter without the prior express written permission of such Person, except as may be required by Applicable Law; [***].
10. **INTELLECTUAL PROPERTY.**
- 10.1. Joint Ownership. Collaborator and MSDIG shall jointly own all rights to all Joint Inventions. [***]. For clarity, the terms of this Agreement do not provide either Party with any right, title or interest or any license to the other Party's intellectual property except as necessary to conduct the MSD Compound Study and as expressly provided under this Agreement, including as set forth in Section 10.8 (Mutual Freedom to Operate).
- 10.2. Right to [***]. Each Party shall have the right to [***].
- 10.3. Prosecution. As necessary following the Effective Date, but in any event as soon as practicable after the discovery of a Joint Invention, patent representatives of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Joint Inventions that may arise. In particular, the Parties shall discuss which Party will file a Joint Patent Application or whether outside counsel will file any such Joint Patent Application. Unless otherwise agreed, the Parties shall appoint mutually-acceptable outside counsel to prosecute and maintain any Joint Patent Applications and Joint Patents. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of each Joint Patent Application and Joint Patent and [***].
- 10.4. Declining to File, Prosecute or Maintain. In the event the [***].
- 10.5. Prohibition of Patenting. Except as expressly provided in Section 10.3 (Prosecution) and in furtherance and not in limitation of Section 9.1 (Confidential Information), each Party agrees [***].
- 10.6. Patent Enforcement.
- 10.6.1. Each Party shall promptly notify the other of any Third-Party Infringement of which such Party becomes aware.

- 10.6.2. [***] shall have the first right to initiate legal action to enforce all Joint Patents and Joint Inventions against Third-Party Infringement resulting [***] or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that [***] fails to initiate or defend such action by the earlier of: (i) [***] days after first being notified or made aware of such Third-Party Infringement; and (ii) [***] days before the expiration date for initiating or defending such action, [***] shall have the right to initiate or defend such action at its sole expense.
- 10.6.3. [***] shall have the first right to initiate legal action to enforce all Joint Patents and Joint Inventions against Third-Party Infringement [***] or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that [***] fails to initiate or defend such action by the earlier of: (i) [***] days after first being notified or made aware of such Third-Party Infringement; and (ii) [***] days before the expiration date for initiating or defending such action, [***] shall have the right to do so at its sole expense.
- 10.6.4. The Parties shall cooperate to jointly control legal action to enforce [***] against any Third-Party Infringement where such Third-Party Infringement results from [***]. Notwithstanding the foregoing, either Party [***] by the earliest of: (i) [***] days after first being notified of such Third-Party Infringement; (ii) [***] days before the expiration date for filing such action; (iii) [***] days before the expiration date for filing an answer to a complaint in a declaratory judgment action; and (iv) [***] days after notice is received, by one Party from other Party, informing such receiving Party that an application has been filed with the U.S. Food & Drug Administration under Section 351(k) of the U.S. Public Health Services Act (42 U.S.C. 262(k)) seeking approval of a biosimilar or interchangeable biological product of the MSD Compound (when MSD is notifying Party) or the Collaborator Compound (when Collaborator is notifying Party), whichever comes first.
- 10.6.5. If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any [***], the other Party agrees to be joined as a party plaintiff if requested and to give the first Party reasonable assistance and authority to file and prosecute the suit. The Party bringing suit shall bear [***].
- 10.7. *Inventions Owned by Each Party.* Notwithstanding anything to the contrary contained in Section 10.1 (Joint Ownership), the Parties agree that all rights to Collaborator Inventions shall be the exclusive property of Collaborator and all rights to MSD Inventions shall be the exclusive property of MSDIG. Each Party shall: (i) be entitled to file and prosecute in its own name Patent Applications in respect of Inventions it owns; and (ii) own Patents that issue from any such Patent Applications. For the avoidance of doubt: (a) any Invention generically encompassing [***]; and (b) any Invention [***], is an MSD Invention. MSD hereby assigns its right, title and interest to any and all Collaborator Inventions to Collaborator, and Collaborator hereby assigns its right, title and interest to any and all MSD Inventions to MSDIG.

- 10.8. Mutual Freedom to Operate. Each Party hereby grants to the other Party a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to the [***] solely for the purposes of: [***]. For clarity, the terms of this Section 10.8 (Mutual Freedom to Operate) do not provide either Party with any rights, title or interest or any license to the Collaborator Background Patents or the MSD Background Patents except as expressly set forth in the previous sentence.
- 10.9. Termination. [***]; provided, however that the license granted in subsection (c) of Section 10.8 (Mutual Freedom to Operate) shall survive such expiration or termination except [***].
- 10.10. Ownership of Other Inventions. Ownership of all Inventions other than Joint Inventions, MSD Inventions and Collaborator Inventions shall be based on inventorship as determined under United States patent law.
11. **REPRINTS; REFERENCES IN PUBLICATION.**
- Consistent with Applicable Law (including copyright law), each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences or symposia relating to the MSD Compound Study that disclose the name of a Party, provided, however, that such use does not constitute an endorsement of any commercial product or service by the other Party.
12. **PUBLICATIONS; PRESS RELEASES.**
- 12.1. Clinical Trial Registry. Collaborator shall register the MSD Compound Study and Collaborator Clinical Trial with the clinical trials registry located at www.clinicaltrials.gov, shall list MSD as a collaborator with respect to the MSD Compound Study, and shall timely publish the results following completion of the MSD Compound Study, after taking appropriate action to secure any intellectual property rights arising from the MSD Compound Study. The results of the MSD Compound Study will be published in accordance with the Protocol.
- 12.2. Publication. Each Party shall use reasonable efforts to publish or present scientific papers with respect to the MSD Compound Study in accordance with accepted scientific practice. The Parties agree that, prior to submission of the results of the MSD Compound Study for publication or presentation or any other dissemination of such results (including oral dissemination), the publishing Party shall invite the other to comment on the content of the material to be published, presented, or otherwise disseminated according to the following procedure:

- 12.2.1. At least [***] days prior to submission for [***], or [***] days prior to submission for presentation of [***], the publishing Party shall provide to the other Party the full details of the proposed publication, presentation, or dissemination in an electronic version as an email attachment. Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation/dissemination for an additional [***] days to allow for actions to be taken to preserve rights for patent protection.
- 12.2.2. The publishing Party shall reasonably consider any request by the other Party made within the periods set forth in Section 12.2.1 to modify the publication and the Parties shall work together to timely resolve any issue regarding the content for publication. Notwithstanding the foregoing, MSD Clinical Data shall be subject to final review and approval by MSD, not to be unreasonably withheld.
- 12.2.3. The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.
- 12.3. Press Releases. Unless otherwise required by Applicable Law, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party. To the extent a Party desires to make such public announcement, such Party shall request permission of the other Party and provide the other Party with a draft thereof for review and comment at least [***] Business Days prior to the date on which such Party would like to make the public announcement.
13. **REPRESENTATIONS AND WARRANTIES; DISCLAIMERS.**
- 13.1. Due Authorization. Each of Collaborator and MSD represents and warrants to the other that: (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms [***].
- 13.2. Compounds.
- 13.2.1. Collaborator Compound. Collaborator hereby represents and warrants to MSD that: (i) Collaborator has the full right, power and authority to grant all of the licenses granted to MSD under this Agreement; (ii) Collaborator Controls the Collaborator Compound; and (iii) at the time of Delivery of the Collaborator Compound, such Collaborator Compound shall have been Manufactured and supplied in compliance with its Specifications and all Applicable Law.

- 13.2.2. MSD Compound. MSD hereby represents and warrants to Collaborator that: (i) MSD has the full right, power and authority to grant all of the licenses granted to Collaborator under this Agreement; (ii) MSD Controls the MSD Compound; and (iii) at the time of Delivery of the MSD Compound, such MSD Compound shall have been Manufactured and supplied in compliance with its Specifications, the Clinical Quality Agreement, and all Applicable Law.
- 13.3. Results. Neither Party undertakes that the MSD Compound Study shall lead to any particular result, nor is the success of the MSD Compound Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Joint Clinical Data or shared Sample Testing Results, nor for advice or information given in connection therewith.
- 13.4. Anti-Corruption.
- 13.4.1. The Parties acknowledge that the corporate policies or Codes of Conduct of Collaborator and MSD and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. Each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the FCPA.
- 13.4.2. Each Party represents and warrants that it and its Related Entities have not, and covenants that it and its Related Entities will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.
- 13.4.3. Neither Party shall contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.
- 13.4.4. Each Party represents and warrants that it: (i) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; (ii) has not employed or subcontracted with any Person for the performance of the MSD Compound Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs; and (iii) has conducted anti-corruption and bribery (e.g. FCPA) due-diligence review of all Third Parties it may hire to act on its behalf in connection with its performance under this Agreement.

- 13.4.5. Each Party represents and warrants that, except as disclosed to the other in writing prior to the Effective Date, such Party: (i) does not have any interest that directly or indirectly conflicts with its proper and ethical performance of this Agreement; (ii) shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (iii) has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of any due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures to the other Party as are necessary to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that prior to hiring or retaining any Government Official to assist in its performance of this Agreement it shall obtain the written consent of the other Party and complete a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official consistent with industry standards. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.
- 13.4.6. Each Party shall have the right during the Term, and for a period of [***] following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit; provided, that absent reasonable cause or unless prohibited by Applicable Law, such other Party is given reasonable advanced written notice of such audit, and such audit is conducted during regular business hours. The auditing Party shall bear all the expenses of such audit.
- 13.4.7. Each Party shall use commercially-reasonable efforts to ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

- 13.4.8. Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of this Section 13.4, such other Party may make full disclosure of such belief and related information (including, if necessary, Confidential Information) needed to support such belief at any time and for any reason to any competent government bodies and agencies, and to anyone else such Party determines in good faith has a legitimate need to know.
- 13.4.9. Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to their performance of any obligations or activities under this Agreement. Each Party shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.
- 13.4.10. Each Party shall have the right to terminate this Agreement immediately in accordance with Section 6.3 (Termination for Breach) in the event of any violation of this Section 13.4 by the other Party.
- 13.5. **DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MSD MAKES NO WARRANTIES, EXPRESS OR IMPLIED WITH RESPECT TO THE MSD COMPOUND, AND COLLABORATOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE COLLABORATOR COMPOUND, IN EACH CASE INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**
14. **INSURANCE; INDEMNIFICATION; LIMITATION OF LIABILITY.**
- 14.1. *Insurance.* Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, a Party shall provide evidence of such insurance.

14.2. Indemnification.

- 14.2.1. Indemnification by Collaborator. Collaborator agrees to defend, indemnify and hold harmless MSD, its Affiliates, and its and their employees, directors, Subcontractors and agents [***].
- 14.2.2. Indemnification by MSD. MSD agrees to defend, indemnify and hold harmless Collaborator, its Affiliates, and its and their employees, directors, Subcontractors and agents [***].
- 14.2.3. Procedure. The obligations of MSD and Collaborator under this Section 14.2 (Indemnification) are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; provided that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner). The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Defending Party shall keep the Other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.
- 14.2.4. MSD Compound Study Subjects. Neither Party shall offer compensation on behalf of the other Party to any MSD Compound Study subject or bind the other Party to any indemnification obligations in favor of any MSD Compound Study subject.

14.3. **LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY, ITS AFFILIATES AND ITS OR THEIR EMPLOYEES DIRECTORS, SUBCONTRACTORS OR AGENTS) BE LIABLE TO THE OTHER PARTY UNDER ANY THEORY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES, ANY PUNITIVE DAMAGES, ANY LOST PROFIT, LOST SALE OR

LOST OPPORTUNITY DAMAGES (WHETHER SUCH CLAIMED DAMAGES ARE DIRECT OR INDIRECT), ARISING DIRECTLY OR INDIRECTLY OUT OF OR RELATED TO THIS AGREEMENT, THE ACTIVITIES TO BE CONDUCTED BY THE PARTIES HEREUNDER OR THE COLLABORATOR CLINICAL TRIAL (INCLUDING THE MSD COMPOUND STUDY). SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH IT IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO USE, DISCLOSURE, LICENSE, [*].**

15. [***]
[***]

16. **FORCE MAJEURE.**

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, acts of terror, governmental action and governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed. The non-performing Party shall notify the other Party of such any such event within [***] days after such occurrence by giving notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

17. **ENTIRE AGREEMENT; AMENDMENT; WAIVER.**

- 17.1. This Agreement, together with the Appendices, Exhibits and Schedules hereto and the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement, [***]. In the event of a conflict between a Related Agreement and this Agreement, the terms of this Agreement shall control except: (i) in the event of any inconsistencies between the terms of this Agreement and the Data Protection Terms [***]; (ii) in the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement [***]. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such

waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

18. **ASSIGNMENT AND AFFILIATES.**

Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign all or any part of this Agreement without the other Party's consent: (i) to one or more of its Affiliates, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided in each case, that such Affiliates agree to be bound by this Agreement; or (ii) to a Person acquiring all or substantially all of its assets to which this Agreement relates, whether by merger, acquisition or similar transaction or series of related transactions. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of the Agreement. Any assignment not in accordance with this Article 18 shall be null, void and of no legal effect.

19. **CHANGE OF CONTROL.**

If Collaborator undergoes a Change of Control in which the Third Party acquirer owns or controls a [***] Antagonist, then upon MSD's request, the Parties shall engage in discussion and effective upon such Change of Control, Collaborator shall maintain, and shall ensure that its Third Party acquirer maintains, reasonable procedures to be agreed with MSD to prevent the disclosure of Sensitive Information beyond Collaborator's personnel having access to or knowledge of Sensitive Information prior to the Change of Control and other personnel of the Third Party acquirer approved by MSD, and to control the dissemination of Sensitive Information disclosed after the Change of Control to prevent the use of Sensitive Information for the development and/or commercialization of competing [***] Antagonist products.

20. **INVALID PROVISION.**

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

21. **GOVERNING LAW; DISPUTE RESOLUTION.**

- 21.1.1. The Parties shall attempt to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles. [***].
- 21.1.2. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

22. **NOTICES.**

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile or email (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Collaborator, to the address(es) set forth in the Collaborator Notice Block on the Information Sheet.

If to MSD, to:

MSD International GmbH

[***]

MSD International Business GmbH

[***]

With copies (which shall not constitute notice) to:

[***]

23. **RELATIONSHIP OF THE PARTIES.**

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or bind the other Party, except with the other Party's express prior written consent. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

24. **COUNTERPARTS AND DUE EXECUTION.**

This Agreement and any amendment may be executed in any number of counterparts (including by [***] electronic transmission), each of which shall be deemed an original, but all of which together constitute one and the same instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. For clarity, facsimile signatures and signatures transmitted by PDF shall be treated as original signatures.

25. **CONSTRUCTION.**

Except where the context otherwise requires, wherever used, the singular includes the plural and vice versa, the use of any gender will be applicable to all genders, and the word “**or**” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “**including**” as used herein shall be deemed to be followed by the phrase “**without limitation**” or like expression. The term “**will**” as used herein means shall. The terms “**hereof**”, “**hereto**”, “**herein**” and “**hereunder**” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement. References to “**Article**,” “**Section**,” “**Exhibit**” or “**Schedule**” are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. A reference to any statute, law, rule, regulation or directive will be construed as a reference to such statute, law, rule, regulation or directive as amended, extended, repealed and replaced or re-enacted from time to time. A definition of or reference to any agreement, instrument or document herein shall refer to such agreement, instrument or other document as it may be amended, supplemented or otherwise modified from time to time (subject to any restrictions on such amendments, supplements or modifications set forth herein). Any reference to “agree,” “consent,” “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging). Except where the context otherwise requires, references to this “**Agreement**” shall include the appendices and schedules attached to this Agreement. The language of this

Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank. Signature page follows.]

Bicara Therapeutics, Inc.

By: [***]
Name: [***]
Title: [***]

MSD International GmbH

By: [***]
Name: [***]
Title: [***]

MSD International Business GmbH

By: [***]
Name: [***]
Title: [***]

[**]

EXHIBIT B
SUPPLY OF COMPOUND

[***]

EXHIBIT C
DATA PROTECTION TERMS

[**]

SCHEDULE I

[**]

SCHEDULE II
SAMPLE TESTING SCHEDULE

[***]

SCHEDULE III

THIRD PARTIES PROVIDING MSD COMPOUND STUDY ACTIVITIES

OFFICE LEASE AGREEMENT

BY AND BETWEEN

COLUMBIA REIT – 116 HUNTINGTON, LLC

a Delaware limited liability company

AND

BICARA THERAPEUTICS INC.,

a Delaware corporation

116 Huntington Avenue

Boston, Massachusetts 02116

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OFFICE LEASE AGREEMENT

THIS OFFICE LEASE AGREEMENT (this “Lease”) is dated as of August 16, 2023 (“Execution Date”), by and between **COLUMBIA REIT – 116 HUNTINGTON, LLC**, a Delaware limited liability company (“Landlord”), and **BICARA THERAPEUTICS INC.**, a Delaware corporation (“Tenant”).

**ARTICLE I
DEFINITIONS**

BASIC DEFINITIONS:

1.1 Reserved.

1.2 Base Rent: the annual amount payable as set forth in the following table:

| Lease Year | Rate Per Rentable Square Foot | Monthly Installment | Annual Installment* |
|-------------------|-------------------------------|---------------------|---------------------|
| LCD-2/29/24** | \$ 70.00 | \$26,932.50 | \$323,190.00 |
| 3/1/24-2/28/25 | \$ 71.40 | \$27,471.15 | \$329,653.80 |
| 3/1/25-2/28/26*** | \$ 72.83 | \$28,021.34 | \$336,256.08 |

* Based on twelve (12) full calendar months.

** Subject to the Abatement Period set forth in Section 4.2.

*** Partial Lease Year

1.3 Base Rent Annual Escalation Percentage: two percent (2%).

1.4 Broker(s): Cushman & Wakefield U.S., Inc. (“Landlord’s Broker”); and Cresa (“Tenant’s Broker”).

1.5 Building: a fifteen (15) story (above grade) building deemed to contain two hundred seventy-two thousand eight hundred seventy-six (272,876) square feet of total rentable area (“Total Area”) located at 116 Huntington Avenue, Boston, Massachusetts 02116, which includes the entirety of the office and commercial space of the Building.

1.6 Building Hours: 8:00 a.m. to 6:00 p.m. Monday through Friday (excluding Holidays) and 9:00 a.m. to 1:00 p.m. on Saturday (excluding Holidays), subject to provisions in Section 14.1 of this Lease.

1.7 Expiration Date: 11:59 p.m. (local time at the Building) on February 28, 2026.

1.8 Guarantor(s): Not applicable.

1.9 Holidays: All holidays recognized by the United States federal government or the Commonwealth of Massachusetts.

1.10 [Reserved]

1.11 **Landlord Notice Address:** Columbia REIT – 116 Huntington, LLC, c/o Columbia Property Trust, Inc., 315 Park Avenue South, Suite 500, New York, N.Y. 10010, Attn: Asset Manager; with copy to LegalNotice@columbia.reit; and with copy to the property manager (currently Columbia Property Trust Services, Inc. at 116 Huntington Avenue, Boston, Massachusetts 02116, Attention: Management Office); and copy to Stroock & Stroock & Lavan, 1875 K Street, N.W., Suite 800, Washington, D.C. 20004, Attention: Jeffrey R. Keitelman, Esq.

1.12 **Landlord Payment Address:**

Via Mail:

Columbia REIT - 116 Huntington, LLC
P.O. Box 28973
New York, NY 10087-8973

Via Overnight Delivery:

JPMorgan Chase-Lockbox Processing
Lockbox: Columbia REIT - 116 Huntington, LLC,
#28973
4 Chase Metrotech Center- 7th Floor East
Brooklyn, NY 11245

Via Wire or Electronic Funds Transfer:

Bank Name - J.P. Morgan Chase
Bank Address - NY, NY
ABA # - 021000021
Account Name - Columbia REIT - 116 Huntington, LLC
Account # - 676335511

At Landlord's option upon at least thirty (30) days' written notice, Tenant shall make all payments by means of electronic transfer of funds or in such other manner as Landlord may from time to time specify in writing.

1.13 **Lease Commencement Date:** 12:01 a.m. (local time at the Building) on the date on which the work and materials to be provided by Landlord as set forth in Section 9.1 are substantially complete. Notwithstanding the foregoing, Tenant shall not have any right to commence use of the Premises unless the same are vacant and delivered to Tenant by Landlord.

1.14 **Lease Term:** Commences on the Lease Commencement Date and continues through the Expiration Date unless sooner terminated in accordance with the terms of this Lease, subject to Section 3.1.

1.15 [Reserved]

1.16 [Reserved]

1.17 **Parking Space Allotment:** Subject to the terms of Section 24.1, one (1) monthly parking permit for unreserved parking in the Parking Facilities.

1.18 **Premises:** deemed to contain four thousand six hundred seventeen (4,617) square feet of rentable area located on a portion of the seventh (7th) floor of the Building, as more particularly designated on **Exhibit A**. The rentable area of the Premises and the Building has been determined by the Building's architect and as of the date hereof is in accordance with the BOMA Standard Method for Measuring Floor Area in Office Buildings (ANSI Z65.1-2010) calculation methodology with accompanying guidelines. In addition, the rentable area of the Building and the Premises (and, accordingly, any other item in this Lease varying with square footage) is subject to adjustment by Landlord due to changes in the measurement, layout, configuration or building amenities of the Building.

1.19 [Reserved]

1.20 **Security Deposit Amount:** One Hundred Thousand and 00/100 Dollars (\$100,000.00).

1.21 **Tenant Notice Address:** 245 Main Street, Cambridge, MA 02142, Attn: Ivan Hyep.

1.22 **Tenant's Proportionate Share:** 1.69% for each of Operating Charges and Real Estate Taxes.

1.23 **Operating Charges Base Year:** calendar year 2023.

1.24 **Real Estate Taxes Base Year:** July 1, 2023 through June 30, 2024 (i.e., City of Boston Fiscal Year 2024).

ADDITIONAL DEFINITIONS:

1.25 **ADA:** the Americans with Disabilities Act and the regulations promulgated thereunder, as the same may be amended from time to time.

1.26 **Affiliate of Tenant:** (i) a corporation, partnership, limited liability company, limited liability partnership, or other business entity (collectively, a "**successor corporation**") into or with which Tenant shall be merged or consolidated, or to which substantially all of the assets of, or control of, Tenant may be transferred or sold, provided that if Tenant is not the surviving corporation, partnership, limited liability company, limited liability partnership or other business entity in such merger or consolidation, or if Tenant transfers all or substantially all of its assets, then in either case such successor corporation either (a) shall have a net worth at least equal to the net worth of Tenant as of the date hereof, or (b) shall be strong financially and creditworthy as reasonably determined by Landlord taking into account the liabilities under this Lease and the fact that the original Tenant under this Lease is not being released, and provided that the successor corporation shall assume in writing all of the obligations and liabilities of Tenant under this Lease (without relieving Tenant therefrom) and the proposed use of the Premises is in compliance with Article VI; or (ii) a corporation or other business entity (a "**related corporation**") which shall control, be controlled by or be under common control with Tenant, and provided that such related corporation shall assume in writing all of the obligations and liabilities of Tenant under this Lease (without relieving Tenant therefrom) and the proposed use of the Premises is in compliance with Article VI. For purposes of this paragraph, "**control**" shall be deemed to be ownership of more than fifty percent (50%) of the stock or other voting interest of the controlled corporation or other business entity.

1.27 **Agents:** any agent, officer, employee, subtenant, assignee, contractor, client, family member, licensee, customer, invitee or guest of a party.

1.28 **Alterations:** any structural or other alterations, decorations, additions, installations, demolitions, improvements or other changes.

1.29 **Reserved.**

1.30 **Bankruptcy Code:** Title 11 of the United States Code, as amended.

1.31 **Building Structure and Systems:** the exterior and common area walls, main lobby in the Building, slab floors, exterior windows, load bearing elements, foundations, roof and common areas that form a part of the Building, and the Building's standard mechanical, electrical, HVAC and plumbing systems, pipes and conduits that are provided by or on behalf of Landlord (or any predecessor) in the operation of the Building.

1.32 **Cabling:** telephone, computer and other communications and data systems and cabling.

1.33 **Case:** a formal proceeding in which Tenant is the subject debtor under the Bankruptcy Code.

1.34 **Common Areas:** those common and public areas and facilities of the Building and improvements to the Land which are from time to time provided by Landlord for the use or benefit of tenants in the Building or for use or benefit by the public in general, including (a) access corridors, elevator foyers and core bathrooms, to the extent the same are not located on floors of the Building fully leased to a single tenant and included in such tenant's premises, and (b) Building-wide mailrooms, fire rooms, vending areas, health and fitness facilities, janitorial areas and other similar facilities of the Building, and (c) any and all non-exclusive grounds, parks, landscaped areas, plazas, outside sitting areas, sidewalks, pedestrian ways, loading docks, and (d) generally all other common and public improvements on the Land.

1.35 **Reserved.**

1.36 **Cosmetic Changes:** those minor, non-structural Alterations of a decorative nature consistent with a first-class office building for which a building permit is not required and which cost (including installation) in the aggregate less than Twenty Five Thousand Dollars (\$25,000) per project or series of related projects, such as painting, carpeting and hanging pictures.

1.37 **Costs:** any costs, damages, claims, liabilities, expenses (including reasonable attorneys' fees), losses, penalties and court costs.

1.38 **Default Rate:** the greater of fifteen percent (15%) per annum or the rate per annum which is five (5) whole percentage points higher than the Prime Rate.

1.39 **Environmental Default:** any of the following by Tenant or any Agent of Tenant: a violation of an Environmental Law; a release, spill or discharge of a Hazardous Material on or from the Premises, the Land or the Building; an environmental condition requiring responsive action; or an emergency environmental condition.

1.40 **Environmental Law:** any present and future Law and any amendments (whether common law, statute, rule, order, regulation or otherwise), permits and other requirements or guidelines of governmental authorities applicable to the Building or the Land and relating to the environment and environmental conditions or to any Hazardous Material (including CERCLA, 42 U.S.C. § 9601 et seq., the Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6901 et seq., the Hazardous Materials Transportation Act, 49 U.S.C. § 1801 et seq., the Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq., the Clean Air Act, 42 U.S.C. § 7401 et seq., the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., the Safe Drinking Water Act, 42 U.S.C. § 300f et seq., the Emergency Planning and Community Right-To-Know Act, 42 U.S.C. § 1101 et seq., the Occupational Safety and Health Act, 29 U.S.C. § 651 et seq., and any so-called "Super Fund" or "Super Lien" law, any Law requiring the filing of reports and notices relating to hazardous substances, environmental laws administered by the Environmental Protection Agency, and any similar state and local Laws, all amendments thereto and all regulations, orders, decisions, and decrees now or hereafter promulgated thereunder concerning the environment, industrial hygiene or public health or safety).

1.41 **Event of Bankruptcy:** the occurrence with respect to any of Tenant, any Guarantor or any other person liable for Tenant's obligations hereunder (including any general partner of Tenant) of any of the following: (a) such person becoming insolvent, as that term is defined in the Bankruptcy Code or Insolvency Laws; (b) appointment of a receiver or custodian for any property of such person, or the institution of a foreclosure or attachment action upon any property of such person; (c) filing by such person of a voluntary petition under the provisions of the Bankruptcy Code or Insolvency Laws; (d) filing of an involuntary petition against such person as the subject debtor under the Bankruptcy Code or Insolvency Laws, which either (1) is not dismissed within sixty (60) days after filing, or (2) results in the issuance of an order for relief against the debtor; (e) such person making or consenting to an assignment for the benefit of creditors or a composition of creditors; (f) such person knowingly submitting (either before or after execution hereof) to Landlord any financial statement containing any material inaccuracy or omission; or (g) an admission by Tenant or any Guarantor of its inability to pay debts as they become due.

1.42 **Event of Default:** any of the following: (a) Tenant's failure to make when due any payment of the Base Rent, additional rent or other sum, which failure shall continue for a period of three (3) days after Landlord sends Tenant written notice thereof (except that Tenant shall not be entitled to any notice and cure period for the third and each subsequent such failure during any twelve month period during the Lease Term); (b) an Event of Bankruptcy; (c) Tenant's dissolution or liquidation; (d) any Environmental Default; (e) any sublease, assignment or mortgage not permitted by Article VII; (f) Tenant's failure to comply with any

provision of Article XI; (g) Tenant's failure to perform or observe any covenant or condition of this Lease not otherwise specifically described above in this definition of "Event of Default," which failure shall continue for a period of ten (10) days after Landlord sends Tenant written notice thereof (or such shorter period as is appropriate if such failure is capable of being cured sooner) (except that Tenant shall not be entitled to any notice and cure period for the third and each subsequent such failure during any twelve month period during the Lease Term); provided, however, that if such cure cannot reasonably be effected within such ten (10) day period and Tenant begins such cure promptly within such ten (10) day period and is pursuing such cure in good faith and with diligence and continuity, then, except in the event of an emergency, Tenant shall have such additional time (not to exceed ninety (90) days in total) as is reasonably necessary to effect such cure.

1.43 **Reserved.**

1.44 **Reserved.**

1.45 **Hazardous Materials:** (a) asbestos and any asbestos containing material and any substance that is then defined or listed in, or otherwise classified pursuant to, any Environmental Law or any other applicable Law as a "hazardous substance," "hazardous material," "hazardous waste," "infectious waste," "toxic substance," "toxic pollutant" or any other formulation intended to define, list, or classify substances by reason of deleterious properties such as ignitability, corrosivity, reactivity, carcinogenicity, toxicity, reproductive toxicity, or Toxicity Characteristic Leaching Procedure (TCLP) toxicity, (b) any petroleum and drilling fluids, produced waters, and other wastes associated with the exploration, development or production of crude oil, natural gas, or geothermal resources, (c) toxic mold, mildew or any substance that reasonably can be expected to give rise to toxic mold or mildew, or (d) any petroleum product, polychlorinated biphenyls, urea formaldehyde, radon gas, radioactive material (including any source, special nuclear, or by-product material), medical waste, chlorofluorocarbon, lead or lead-based product, and any other substance whose presence could be detrimental to the Building or the Land or hazardous to health or the environment.

1.46 **including:** including, but not limited to; including, without limitation; and words of similar import.

1.47 **Insolvency Laws:** the insolvency Laws of any state.

1.48 **Landlord Insured Parties:** Landlord's Representatives, the managing agent of the Building and the holder of any Mortgage, in each case of whom Landlord shall have given notice to Tenant, and any other party that Landlord may reasonably designate in writing from time to time.

1.49 **Landlord's Representatives:** Landlord's affiliates, shareholders, partners, directors, officers, employees, agents and representatives.

1.50 **Reserved.**

1.51 **Laws:** all present and future laws, ordinances (including zoning ordinances and land use requirements), regulations, orders and recommendations (including those made by any public or private agency having authority over insurance rates).

1.52 **Lease Year:** a period of twelve (12) consecutive months commencing on the Lease Commencement Date, and each successive twelve (12) month period thereafter; provided, however, that if the Lease Commencement Date is not the first day of a month, then the second Lease Year shall commence on the first day of the month following the month in which the first anniversary of the Lease Commencement Date occurs (e.g., if the Lease Commencement Date is September 15, 2023, the second Lease Year will begin October 1, 2023).

1.53 **Mortgages:** all mortgages, deeds of trust, deeds to secure debt, ground leases, or other security instruments which may now or hereafter encumber any portion of the Building or the Land.

1.54 **Operating Charges:** all expenses, charges and fees incurred by or on behalf of Landlord in connection with the management, operation, ownership, maintenance, servicing, insuring and repair of the Building (which is deemed to include the site upon which the Building is constructed (which site is sometimes referred to herein as the "**Land**"), the roof of the Building and any physical extensions therefrom, any driveways, sidewalks, landscaping and parking facilities in the Building or on the Land, and all other areas, facilities, improvements and appurtenances relating to any of the foregoing) including the following: (1) electricity with respect to the Common Areas and the Building systems (as reasonably determined by Landlord), gas, water, HVAC (including chilled condenser water), sewer and other utility and service costs, charges and fees (including any tap fees and connection and switching fees) of every type and nature; (2) premiums, deductibles and other charges for insurance; (3) management fees of not more than three percent (3%) of the adjusted gross revenues of the Building (plus amounts that would have been received had there been no rental abatements or other concessions); (4) costs of service, equipment rental, access control, landscaping and maintenance contracts; (5) maintenance, repair and (subject to the limitations on capital expenditures set forth below) replacement expenses and supplies; (6) depreciation/amortization for capital expenditures made by Landlord to reduce operating expenses or to comply with Laws imposed after the date hereof, which shall be charged in annual installments over the useful life of the items for which such costs are incurred (provided that in the case of capital expenditures reasonably estimated to reduce operating expenses, Landlord shall have the right to amortize such expenses in annual installments equal to the projected annual savings) together with interest, each calendar year such costs are charged to Operating Charges, on the unamortized balance at an interest rate of two percent (2%) in excess of the Prime Rate in effect on January 1 of each calendar year; (7) charges for janitorial and cleaning services and supplies; (8) any business, professional or occupational license tax payable by Landlord with respect to the Building and any association fees; (9) [reserved]; (10) sales, use and personal property taxes payable in connection with tangible personal property and services purchased for and used in connection with the Building; (11) reasonable third party accounting and audit fees relating to the determination of Operating Charges (and tenants' proportionate shares thereof) and the preparation of statements required by tenant leases; (12) expenses incurred in connection with concierge services provided to the Building (if any); (13) the fair market rental value of any management office (of reasonable and

customary size) and fitness facilities in the Building; (14) special assessments, fees, penalties and other charges and costs for transit, transit encouragement traffic reduction programs, or any similar purpose; (15) all costs of operating, maintaining, repairing and replacing equipment in any portion of any fitness facility, roof deck, function room, conference facility or other amenity of the Building (to the extent not offset by separate membership or usage fees imposed by Landlord); (16) payments or assessments required in connection with a reciprocal easement or similar agreement to which the Landlord or the Building is bound; (17) any other expense incurred by Landlord in arm's-length transactions in connection with maintaining, repairing or operating the Building; (18) costs and expenses for the maintenance and operation of parking areas and facilities and other parking arrangements for the Building for any transportation demand management program therefor, and for the maintenance and operation of shuttle bus and other transportation programs or facilities therefor; (19) all costs (including all fringe benefits, workers' compensation insurance premiums and payroll taxes) of employees at or below the level of property manager that are exclusively employed at the Building; and (20) all common area expenses and any and all other operating, management and other amounts imposed under private assessments and allocable to the Building. Notwithstanding any provision contained in this Lease to the contrary, Operating Charges shall not include: (i) Real Estate Taxes; (ii) principal or interest payments on any Mortgage; (iii) the costs of special services and utilities separately charged to particular tenants of the Building; (iv) base rent or percentage rent payments under any ground lease; (v) advertising and promotional expenses directly relating to leasing; (vi) costs for which Landlord is reimbursed by insurance proceeds or from tenants of the Building (other than such tenants' regular contributions to Operating Charges); (vii) costs directly and solely related to the maintenance and operation of the entity that constitutes the Landlord, such as accounting fees incurred solely for the purpose of reporting Landlord's financial condition; (viii) costs of repairs, replacements or other work occasioned by fire, windstorm or other casualty, or the exercise by governmental authorities of the right of eminent domain (except for the deductible under any insurance carried by Landlord); (ix) leasing commissions, attorney's fees, costs, disbursements and other expenses incurred by Landlord or its agents in connection with negotiations for leases with tenants, other occupants or prospective tenants or other occupants of the Building, and similar costs incurred in connection with disputes with and/or enforcement of any leases with tenants, other occupants, or prospective tenants or other occupants of the Building; (x) tenant allowances, tenant concessions, and other costs and expenses (including permit, license and inspection fees) incurred in connection with completing, fixturing, furnishing, renovating or otherwise improving, decorating or redecorating leased premises for tenants or other occupants, or vacant, leasable space in the Building, including space planning/interior architecture fees and/or engineering for same; (xi) costs or expenses (including fines, penalties and legal fees) incurred due to the violation (as compared to compliance costs) by Landlord, its agents or employees, any tenant (other than Tenant) or other occupant of the Building of any terms and conditions of this Lease or of the leases of other tenants in the Building, and/or of any valid applicable Laws that would not have been incurred but for such violation by Landlord, its agent or employee, tenant, or other occupant, it being intended that each party shall be responsible for the costs resulting from its violation of such leases and Law (provided that reasonable attorneys' fees to enforce rules and regulations for the Building shall be included in Operating Charges); (xii) penalties for any late payment by Landlord, including taxes and equipment leases; (xiii) compensation paid to clerks, attendants or other persons in commercial concessions (such as a snack bar, restaurant or newsstand, but not

including Building amenities such as the fitness facility and the Parking Facilities, or any roof deck, function room, or conference facility); (xiv) Landlord's contributions to charitable organizations; (xv) costs of correcting defects, including any allowances for same, in the original construction of the Building; (xvi) costs in connection with services (including electricity), items or other benefits of a material type which are not available to Tenant without specific charge therefor, but which are provided to another tenant or occupant of the Building, whether or not such other tenant or occupant is specifically charged therefor by Landlord; (xvii) costs or expenses for the purchase or leasing of sculpture, paintings or other works of art, other than normal building decorations customary in projects comparable to the Building; and (xviii) reserves of any kind; and (xix) costs arising from the presence of Hazardous Materials in, about or below the Land or the Building (including any Hazardous Materials brought to, deposited on or disposed of at the Building by Landlord or its employees, agents, or contractors, but excluding those Hazardous Materials utilized in connection with the operation, maintenance and repair of the Building in the ordinary course and those brought, deposited or disposed of by Tenant or Tenant's Agents with respect to its use or occupancy of space in the Building).

1.55 **Parking Facilities:** the parking areas in the garage adjacent to the Building, including such valet arrangements, if any, as may be provided or permitted pursuant thereto.

1.56 **Prime Rate:** the prime rate published in the Money Rates section of the Wall Street Journal.

1.57 [Reserved]

1.58 **Proposed Sublease Commencement Date:** the anticipated commencement date of the proposed assignment, subletting or other transaction.

1.59 **Proposed Sublet Space:** the area proposed to be assigned, sublet or otherwise encumbered.

1.60 **Proposed Sublet Term:** the term for which the Proposed Sublet Space is proposed to be assigned, sublet or otherwise encumbered.

1.61 **Real Estate Taxes:** (1) all of the real estate taxes and assessments imposed upon or with respect to the Building or Landlord's interest therein; (2) any assessment, tax, fee, levy or charge in addition to, or in substitution, partially or totally, of any assessment, tax, fee, levy or charge previously included within the definition of real property tax, it being acknowledged by Tenant and Landlord that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such services as (without limitation) fire protection, street, sidewalk and road maintenance, refuse removal and for other governmental services formerly provided without charge to property owners or occupants, and Real Estate Taxes shall also include any governmental or private assessments or the contribution by the Building towards a governmental or private cost-sharing agreement for the purpose of augmenting or improving the quality of services and amenities normally provided by governmental agencies; (3) any assessment, tax, fee, levy, or charge allocable to or measured by the area of the Premises, or the rent or additional rent payable hereunder, including, without limitation, any business or gross income tax, gross receipts tax or excise tax with respect to the receipt of such rent, or upon or with respect to the

possession, leasing, operating, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises, or any portion thereof; and (4) reasonable expenses (including reasonable attorneys' and consultants' fees and court costs, provided that attorneys' fees may be on a contingent fee basis) incurred in reviewing, protesting or seeking a reduction or abatement of, or defending or otherwise participating in any challenge to, real estate taxes, whether or not such protest or reduction is ultimately successful (provided, however, that such review, protest, or reduction attempt is undertaken in good faith by Landlord with the reasonable expectation to reduce Real Estate Taxes for the Building). Real Estate Taxes shall not include any inheritance, estate, gift, franchise, corporation, net income or net profits tax assessed against Landlord from the operation of the Building, or any interest charges or penalties incurred as a result of Landlord's failure to timely pay Real Estate Taxes (provided that if the taxing authority permits a taxpayer to elect to pay in installments, then, for purposes of determining the amount of Real Estate Taxes, if Landlord so elects to pay in installments, all interest charges shall be deemed Real Estate Taxes).

1.62 Reconciliation Statement: a reasonably detailed written statement showing (1) Tenant's Proportionate Share of the amount by which (A) Operating Charges incurred during the immediately preceding calendar year exceeded the Operating Charges Base Amount (as defined in Section 5.2(a)), and (B) Real Estate Taxes for the immediately preceding calendar year exceeded the Real Estate Taxes Base Amount (as defined in Section 5.3(a)), as applicable; and (2) the aggregate amount of Tenant's estimated payments made on account of Operating Charges and Real Estate Taxes during such year, as applicable.

1.63 Structural and System Alterations: any Alteration that will or may necessitate any changes, replacements or additions to the load-bearing or exterior walls, non-drop ceilings, partitions (load-bearing or non-demising), columns or floor, or to the fire protection, water, sewer, electrical, mechanical, plumbing, HVAC or other base building systems, of the Premises or the Building.

1.64 Tenant Items: all non-Building standard supplemental heating, ventilation and air conditioning equipment and systems serving exclusively the Premises and any special tenant areas, facilities and finishes, any special fire protection equipment, any telecommunications, security, data, computer and similar equipment, cabling and wiring, kitchen/galley equipment and fixtures, all other furniture, furnishings, equipment and systems of Tenant and all Alterations.

1.65 Tenant's Sublease Request Notice: a notice to Landlord containing: the identity of a proposed assignee, subtenant or other party and its business; the terms of the proposed assignment, subletting or other transaction (including a copy of the proposed document for same); the Proposed Sublease Commencement Date; the Proposed Sublet Space; the Proposed Sublet Term, financial statements for the prior two (2) years certified by an authorized officer of Tenant or a certified public accounting firm, or other evidence of financial responsibility of such proposed assignee, subtenant or other party; and a certification executed by Tenant and such party stating whether or not any premium or other consideration is being paid for the assignment, sublease or other transaction.

1.66 Reserved.

1.67 Trustee: a trustee-in-bankruptcy of Tenant under a Case.

ARTICLE II
PREMISES

2.1 Tenant leases the Premises from Landlord for the term and upon the conditions and covenants set forth in this Lease. Except as may otherwise be expressly provided in this Lease, the lease of the Premises does not include the right to use the roof, mechanical rooms, electrical closets, janitorial closets, telephone rooms, parking areas or non-common or non-public areas of any portion of the Building, whether or not any such areas are located within the Premises. However, Tenant shall have the non-exclusive right to use: (1) the plenums, risers, electrical closets, telephone rooms, ducts or pipes on or serving the floor on which the Premises are located (other than those installed for another tenant's exclusive use and provided Tenant shall have such utilization in no greater proportion than the ratio by which the square feet of rentable area in the Premises compares to the square feet of rentable area in the Building) in accordance with plans and specifications to be approved by Landlord in its sole discretion; (2) the Parking Facilities in accordance with Article XXIV; and (3) any mechanical rooms, electrical closets and telephone rooms located within the Premises, for the purpose for which they were intended, but only with Landlord's prior consent (except to the extent that such rooms and closets contain no system, wiring or other item related to either the Building Structure and Systems or to a structure or system of any tenant or occupant other than Tenant, in which case no such prior consent of Landlord shall be required for use by Tenant's on-site, properly licensed and trained technicians) and strictly in accordance with Landlord's rules, regulations and requirements in connection therewith.

ARTICLE III
TERM

3.1 All of the provisions of this Lease shall be in full force and effect from and after the Execution Date. The Lease Term shall commence on the Lease Commencement Date and expire at 11:59 P.M. on the Expiration Date. If the Lease Commencement Date is not the first day of a month, then the Lease Term shall be the period set forth in Section 1.14 plus the partial month in which the Lease Commencement Date occurs. The Lease Term shall also include any properly exercised renewal or extension of the term of this Lease.

3.2 Promptly after the Lease Commencement Date is ascertained, Landlord and Tenant shall execute the certificate attached to this Lease as **Exhibit D**. Failure to execute said certificate shall not affect the commencement or expiration of the Lease Term.

ARTICLE IV
BASE RENT

4.1 From and after the Lease Commencement Date, Tenant shall pay the Base Rent in equal monthly installments in advance on the first day of each month during a Lease Year.

4.2 Notwithstanding the foregoing, provided no Event of Default by Tenant has occurred under this Lease, Landlord grants to Tenant an abatement of the Base Rent otherwise payable hereunder for the first one and one-half (1½) calendar months of the Lease Term (the "Abatement Period"). Concurrently with Tenant's execution of this Lease, Tenant shall pay an amount equal to one (1) monthly installment of the Base Rent payable during the first Lease Year, which amount shall be credited toward the monthly installment of Base Rent payable for the first full calendar month of the Lease Term following the expiration of the Abatement Period. If the Lease Commencement Date is not the first day of a month, then the Base Rent from the Lease Commencement Date until the first day of the following month shall be prorated on a per diem basis at the rate of one thirtieth (1/30th) of the monthly installment of the Base Rent payable during the first Lease Year, and Tenant shall pay such prorated installment of the Base Rent on the Lease Commencement Date.

4.3 All sums payable by Tenant under this Lease shall be paid to Landlord in legal tender of the United States, without setoff, deduction or demand, at the Landlord Payment Address, or to such other party or such other address as Landlord may designate in writing. Landlord's acceptance of rent after it shall have become due and payable shall not excuse a delay upon any subsequent occasion or constitute a waiver of any of Landlord's rights hereunder. If any sum payable by Tenant under this Lease is paid by check which is returned due to insufficient funds, stop payment order, or otherwise, then: (a) such event shall be treated as a failure to pay such sum when due; and (b) in addition to all other rights and remedies of Landlord hereunder, Landlord shall be entitled (i) to impose a returned check charge of Fifty Dollars (\$50.00) to cover Landlord's administrative expenses and overhead for processing, and (ii) to require that all future payments be remitted by wire transfer, money order, or cashier's or certified check.

4.4 Landlord and Tenant agree that no rental or other payment for the use or occupancy of the Premises is or shall be based in whole or in part on the net income or profits derived by any person or entity from the Building or the Premises. Tenant will not enter into any sublease, license, concession or other agreement for any use or occupancy of the Premises which provides for a rental or other payment for such use or occupancy based in whole or in part on the net income or profits derived by any person or entity from the Premises so leased, used or occupied. Nothing in the foregoing sentence, however, shall be construed as permitting or constituting Landlord's approval of any sublease, license, concession, or other use or occupancy agreement not otherwise approved by Landlord in accordance with the provisions of Article VII.

ARTICLE V
OPERATING CHARGES AND REAL ESTATE TAXES

5.1 For purposes of this Article V, the term "**Building**" shall be deemed to include the **Land**, the roof of the Building and any physical extensions therefrom, any driveways, sidewalks, landscaping, alleys and parking facilities in the Building or on the Land, and all other areas, facilities, improvements and appurtenances relating to any of the foregoing. If the Building is operated as part of a complex of buildings or in conjunction with other buildings or parcels of land, Landlord shall prorate the common expenses and costs with respect to each such building or parcel of land in its sole but reasonable judgment.

5.2 (a) From and after the day following the last day of the Operating Charges Base Year, subject to Section 5.4 below, Tenant shall pay as additional rent Tenant's Proportionate Share of the amount by which Operating Charges for each calendar year falling entirely or partly within the Lease Term exceeds a base amount (the "**Operating Charges Base Amount**") equal to the Operating Charges incurred during the Operating Charges Base Year. Tenant's Proportionate Share with respect to Operating Charges set forth in Article I has been calculated to be that percentage which is equal to a fraction, the numerator of which is the number of square feet of rentable area in the Premises as set forth in the definition of the term "Premises" in Article I, and the denominator of which is the number of square feet of Total Area.

(b) If the average occupancy rate for the Building during any calendar year during the Lease Term (including the Operating Charges Base Year) is less than ninety-five percent (95%), or if any tenant is separately paying for (or does not require), janitorial or other utilities or services furnished to its premises, then Landlord shall include in Operating Charges for such year all additional expenses, as reasonably estimated by Landlord, which would have been incurred during such year if such average occupancy rate had been ninety-five percent (95%) and if Landlord paid for such utilities or services furnished to such premises.

(c) Tenant shall make estimated monthly payments to Landlord on account of Tenant's Proportionate Share of the amount by which Operating Charges that are expected to be incurred during each calendar year would exceed the Operating Charges Base Amount. At the beginning of each calendar year after the Operating Charges Base Year, Landlord shall submit a reasonably detailed written statement setting forth Landlord's reasonable estimate of Tenant's Proportionate Share thereof. Tenant shall pay to Landlord on the first day of each month following receipt of such statement, until Tenant's receipt of the succeeding annual statement, an amount equal to one twelfth (1/12) of each such share (estimated on an annual basis without proration pursuant to Section 5.4). If Landlord does not provide Tenant with an updated estimate in any calendar year during the Lease Term, Tenant shall continue to pay monthly installments based on the most recent estimate(s) until Landlord provides Tenant with the new estimate. Not more than twice during any calendar year, Landlord may revise Landlord's estimate and adjust Tenant's monthly payments to reflect Landlord's revised estimate. Within one hundred twenty (120) days after the end of each calendar year, or as soon thereafter as is feasible, Landlord shall submit a Reconciliation Statement for Operating Charges. If such Reconciliation Statement indicates that the aggregate amount of such estimated payments exceeds Tenant's actual liability, then Landlord shall credit the net overpayment toward Tenant's next installment(s) of rent due under this Lease, or, if the Lease Term has expired or will expire before such credit can be fully applied, or if Tenant is not otherwise liable to Landlord for further payment, Landlord shall reimburse Tenant for the amount of such overpayment within thirty (30) days. If such statement indicates that Tenant's actual liability exceeds the aggregate amount of such estimated payments, then Tenant shall pay the amount of such excess as additional rent.

5.3 (a) From and after the day following the last day of the Real Estate Taxes Base Year, subject to Section 5.4, Tenant shall pay as additional rent Tenant's Proportionate Share of the amount by which Real Estate Taxes for each calendar year falling entirely or partly within the Lease Term exceeds a base amount (the "**Real Estate Taxes Base Amount**") equal to the Real Estate Taxes incurred during the Real Estate Taxes Base Year. Tenant's Proportionate Share with respect to Real Estate Taxes set forth in Article I has been calculated to be that percentage which is equal to a fraction, the numerator of which is the number of square feet of rentable area in the Premises as set forth in Article I above, and the denominator of which is the number of square feet of Total Area. Tenant shall not initiate or participate in any contest of Real Estate Taxes without Landlord's prior written consent.

(b) Tenant shall make estimated monthly payments to Landlord on account of Tenant's Proportionate Share of the amount by which Real Estate Taxes that are expected to be incurred during each calendar year would exceed the Real Estate Taxes Base Amount. At the beginning of each calendar year after the Real Estate Taxes Base Year, Landlord shall submit a reasonably detailed written statement setting forth Landlord's reasonable estimate of Tenant's Proportionate Share thereof. Tenant shall pay to Landlord on the first day of each month following receipt of such statement, until Tenant's receipt of the succeeding annual statement, an amount equal to one twelfth (1/12) of such share (estimated on an annual basis without proration pursuant to Section 5.4). If Landlord does not provide Tenant with an updated estimate in any calendar year during the Lease Term, Tenant shall continue to pay monthly installments based on the most recent estimate(s) until Landlord provides Tenant with the new estimate. Not more than twice during any calendar year, Landlord may revise Landlord's estimate and adjust Tenant's monthly payments to reflect Landlord's revised estimate. Within one hundred twenty (120) days after the end of each calendar year, or as soon thereafter as is feasible, Landlord shall submit a Reconciliation Statement for Real Estate Taxes. If such Reconciliation Statement indicates that the aggregate amount of such estimated payments exceeds Tenant's actual liability, then Landlord shall credit the net overpayment toward Tenant's next installment(s) of rent due under this Lease, or, if the Lease Term hereof has expired or will expire before such credit can be fully applied, of if Tenant is not otherwise liable for further payment, Landlord shall reimburse Tenant for the amount of such overpayment within thirty (30) days. If such statement indicates that Tenant's actual liability exceeds the aggregate amount of such estimated payments, then Tenant shall pay the amount of such excess as additional rent.

5.4 If Tenant's obligations under this Article I commence or expire on a day other than the first day or the last day of a calendar year, respectively, then Tenant's liabilities pursuant to this Article for such calendar year shall be the amount that Tenant would have owed hereunder for the full calendar year had such calendar year fallen entirely within the Lease Term, multiplied by a fraction, the numerator of which is the number of days during such calendar year falling within the Lease Term, and the denominator of which is three hundred sixty five (365).

5.5 Provided that no Event of Default exists and Tenant has timely paid the amount set forth in the applicable Reconciliation Statement, Tenant, through an independent, nationally recognized certified public accountant on behalf of Tenant who is hired by Tenant on a non-contingent fee basis, offers a full range of accounting services and is otherwise approved by Landlord, shall have the right, during regular business hours, at the management office for the Building, and after giving at least thirty (30) days' advance written notice to Landlord, to commence to have Landlord's books and records related to Operating Charges for the immediately preceding calendar year reviewed (and if so commenced, to expeditiously and diligently pursue such review to completion), provided that such review shall be concluded by not later than sixty (60) days following the date Tenant has commenced such review (but in no event later than ninety (90) days following the date of Tenant's receipt of the applicable Reconciliation Statement for the year to which such review and that substantially all of the

communications with Landlord (and Landlord's representatives) in connection with the review shall be conducted by an employee of Tenant; or, at Landlord's sole discretion and in lieu of such review, Landlord shall provide Tenant with an audited statement, the expense of which shall be included within the definition of Operating Charges. If Landlord disagrees with the results of Tenant's review, then Landlord and Tenant's auditor shall together select a neutral auditor of similar qualifications to conduct a review of such books and records (the fees of such neutral auditor to be shared equally by Landlord and Tenant), and the determination of Operating Charges reached by such neutral auditor shall be final and conclusive. If the amounts paid by Tenant to Landlord on account of Operating Charges (a) exceed the amounts to which Landlord is entitled hereunder then Landlord shall, upon its final determination, promptly reimburse such overpayment Tenant, or (b) are less than the amounts to which Landlord is entitled hereunder, then Tenant shall pay such deficiency as additional rent. All costs and expenses of any such review or audited statement shall be paid by Tenant; provided, however, that if the aggregate amount of Operating Charges set forth in such statement was overstated by Landlord by more than five percent (5%) on a cumulative basis for the period audited, Landlord shall reimburse Tenant for the commercially reasonable, out of pocket hourly or flat fee costs and expenses paid by Tenant in connection with Tenant's review (up to a maximum amount of \$5,000). Any and all information obtained through any review (including, without limitation, any matters pertaining to Landlord, its managing agent or the Building), and any compromise, settlement or adjustment that may be proposed or reached between Landlord and Tenant, shall be held in strict confidence, and neither Tenant nor any of Tenant's Agents shall disclose any such information to any person or entity other than a Permitted Recipient on a need to know basis. Tenant shall cause any of Tenant's Agents (including its auditor and any of its brokers) to be similarly bound by this subsection. A "Permitted Recipient" shall be the officers, partners and senior level employees of Tenant who are involved in lease administration, Tenant's certified public accountants who have responsibilities related to Operating Charges, any employees of Tenant's auditor involved with the review, or any person or entity to whom disclosure is required by applicable judicial or governmental authority. Prior to disclosing any such information to any Permitted Recipient (including its auditor), Tenant shall instruct such Permitted Recipient to abide by this confidentiality provision, and, at Landlord's sole option, as a condition precedent to Tenant's right to review Operating Charges as set forth herein, Tenant shall deliver to Landlord a signed covenant from the auditor and any other Permitted Recipient on Landlord's standard form acknowledging all of the conditions of this Section. Notwithstanding anything herein to the contrary, if Tenant does not notify Landlord in writing of any objection to an annual Operating Charges statement within thirty (30) days after receipt thereof, then Tenant shall be deemed to have waived any such objection and shall have no right to review pursuant to this subsection. The rights created in this Section 5.5 are personal to Tenant and may not be exercised more than once in any calendar year.

ARTICLE VI
USE OF PREMISES

6.1 Tenant shall use and occupy the Premises solely for general (non-medical and non-governmental) office purposes compatible with first class office buildings in the Building's submarket, and for no other use or purpose. Tenant shall not use or occupy the Premises for any unlawful purpose, or in any manner that will violate the certificate of occupancy for the Premises

or the Building, or that will constitute waste, nuisance or unreasonable annoyance to Landlord or any other tenant or user of the Building, or in any manner that will increase the number of parking spaces required for the Building or its full occupancy as required by law. Landlord at its expense (subject to reimbursement pursuant to Article V, if and to the extent permitted thereby) shall comply with all Laws to the extent the same apply directly to the Building Structure and Systems and Common Areas as a whole; provided, however, that to the extent any non-compliance is a result of the use or occupancy of the Premises or any action or inaction of Tenant or any Agent of Tenant, or if any improvements made by Landlord to comply with such Laws benefit solely the Premises, then such compliance shall be at Tenant's cost. Tenant shall comply with all Laws concerning the use, occupancy and condition of the Premises and all machinery, equipment, furnishings, fixtures and improvements therein, all in a timely manner at Tenant's sole expense. If any Law requires an occupancy or use permit or license for the Premises or the operation of the business conducted therein, then Tenant shall obtain and keep current such permit or license at Tenant's expense and shall promptly deliver a copy thereof to Landlord. Without limiting the generality of any of the foregoing: Tenant, at its expense, shall install and maintain fire extinguishers and other fire protection devices as may be required with respect to Tenant's use of the Premises from time to time by any agency having jurisdiction thereof and/or the underwriters insuring the Building; and Tenant at its sole cost and expense shall be solely responsible for taking any and all measures which are required to comply with the ADA concerning the Premises (including suite entry doors and related items) and the business conducted therein. Any Alterations made or constructed by or for Tenant for the purpose of complying with the ADA or which otherwise require compliance with the ADA shall be done in accordance with this Lease; provided, that Landlord's consent to such Alterations shall not constitute either Landlord's assumption, in whole or in part, of Tenant's responsibility for compliance with the ADA, or representation or confirmation by Landlord that such Alterations comply with the provisions of the ADA. Use of the Premises is subject to all covenants, conditions and restrictions of record. Tenant shall not use any space in the Building or the Land for the sale of goods to the public at large or for the sale at auction of goods or property of any kind. Tenant shall not conduct any operations, sales, promotions, advertising or special events outside the Premises, in the Building or on the Land.

6.2 Tenant shall pay before delinquency any business, rent or other taxes or fees that are now or hereafter levied, assessed or imposed upon Tenant's use or occupancy of the Premises, the conduct of Tenant's business at the Premises, or Tenant's equipment, fixtures, furnishings, inventory or personal property. If any such tax or fee is enacted or altered so that such tax or fee is levied against Landlord or so that Landlord is responsible for collection or payment thereof, then Tenant shall pay as additional rent the amount of such tax or fee. In addition to Base Rent and other charges to be paid by Tenant hereunder, Tenant shall reimburse Landlord upon demand for any and all taxes or assessments payable by Landlord by applicable Laws, whether or not now customary or within the contemplation of the parties hereto, to the extent not included in Real Estate Taxes: (a) upon, measured by or reasonably attributable to the cost or value of Tenant's equipment, furniture, fixtures and other personal property located in the Premises or by the cost or value of any improvements made in or to the Premises by Tenant regardless of whether title to such improvements shall be in Tenant or Landlord; (b) upon or measured by the rental, parking fees and other charges payable hereunder in the nature of a sales tax upon rent, fees or other charges or a so-called "rent tax" or as a substitute for or in lieu of any

increase in any taxes now in effect in connection with the payment of rent or other charges for the use, occupancy, possession or tenancy of the demised premises for each month or portion thereof during the term of this Lease, but not federal or state income taxes of Landlord; and (c) upon this transaction or any document to which Tenant is a party creating or transferring an interest in the Premises. Tenant agrees to pay all sales taxes and rent taxes in the manner and in accordance with the requirements of applicable Laws. If the applicable taxing authority shall require Landlord or Landlord's agent to collect any sales taxes or rent taxes for or on behalf of the applicable taxing authority, then such sales taxes or rent taxes shall be paid by Tenant to Landlord or Landlord's agent monthly with the rent payments and other charges required to be paid hereunder, in accordance with the requirements of the applicable taxing authority. In the event that it shall not be lawful for Tenant so to reimburse Landlord, the monthly rental payable to Landlord under this Lease shall be revised to net Landlord the same net rental after imposition of any such tax upon Landlord as would have been payable to Landlord if such tax had not been imposed.

6.3 Tenant shall not allow, cause or permit any Hazardous Materials to be generated, used, treated, released, stored or disposed of in or about the Building or the Land, provided that Tenant may use and store normal and reasonable quantities of standard cleaning and office materials in the Premises as may be reasonably necessary for Tenant to conduct normal general office use operations in the Premises so long as such materials are properly, safely and lawfully stored, used and disposed of by Tenant and the quantity of same does not equal or exceed a "reportable quantity" as defined in 40 C.F.R. 302 and 305, as amended. At the expiration or earlier termination of this Lease, with respect to conditions existing on account of Tenant's use or occupancy of the Premises or any action or inaction of Tenant or any Agent of Tenant (it being understood that the term "inaction" as used in this Section shall not impose upon Tenant any obligation to remove Hazardous Materials existing in the Premises as of the Lease Commencement Date which were introduced into the Premises by anyone other than Tenant or any Agent of Tenant, unless such condition is knowingly aggravated as a result of Tenant's use or occupancy of the Premises), Tenant shall surrender the Premises to Landlord free of Hazardous Materials and in compliance with all Environmental Laws. Tenant shall: (i) give Landlord immediate verbal and follow up written notice of any actual or threatened Environmental Default with respect to conditions existing on account of Tenant's use or occupancy of the Premises or any action or inaction of Tenant or any Agent of Tenant, which Environmental Default Tenant shall cure in accordance with all Environmental Laws and only after Tenant has obtained Landlord's prior written consent, which shall not be unreasonably withheld, conditioned or delayed; and (ii) promptly deliver to Landlord copies of any notices or other items received from or submitted to any governmental or quasi-governmental agency, or any claim instituted or threatened by any third party, concerning the Premises, the occupancy or use thereof, or the existence or potential existence of Hazardous Materials therein. Upon any Environmental Default, in addition to all other rights available to Landlord under this Lease, at law or in equity, Landlord shall have the right but not the obligation to immediately enter the Premises, to supervise and approve any actions taken by Tenant to address the Environmental Default, and, if Tenant fails to immediately address same in accordance with this Lease, to perform, with respect to conditions existing on account of Tenant's use or occupancy of the Premises or any action or inaction of Tenant or any Agent of Tenant, at Tenant's sole cost and expense, any lawful action necessary to address same.

ARTICLE VII
ASSIGNMENT AND SUBLETTING

7.1 Except as otherwise expressly provided in this Lease, Tenant shall not assign, transfer or otherwise encumber, including an assignment or transfer by operation of law (collectively, “**assign**”) this Lease or all or any of Tenant’s rights hereunder or interest herein, or sublet or permit anyone to use or occupy (collectively, “**sublet**”) the Premises or any part thereof, without obtaining the prior written consent of Landlord, which consent may be withheld or granted in Landlord’s sole discretion (subject to the remainder of this Article VII). Notwithstanding any of the foregoing to the contrary, provided no Event of Default exists under this Lease, and subject to Landlord’s rights and Tenant’s obligations pursuant to Sections 7.3, 7.4 and 7.5 below, Landlord shall not unreasonably withhold, condition or delay its consent to any proposed subletting of the entire or any portion of the Premises or assignment of the Lease in its entirety. For purposes of the immediately preceding sentence, it shall be reasonable for Landlord to withhold its consent if, for example: (i) the proposed subtenant or assignee is engaged in a business, or the Premises will be used in a manner, that is inconsistent with the first class image of the Building; or (ii) Landlord is not reasonably satisfied with the financial condition of the proposed subtenant or assignee; or (iii) the proposed use of the Premises is not in compliance with Article VI or is not compatible with the other uses within, and the terms of other leases with respect to, the Building; or (iv) the proposed subtenant or assignee is a governmental or quasi- governmental agency; or (v) the holders of Mortgages encumbering the Building shall fail to consent (Landlord hereby agreeing to use commercially reasonable efforts to obtain such consent if Landlord approves such transaction); or (vi) the proposed subtenant or assignee is either (A) an existing tenant of the Building (or any parent, subsidiary or affiliate thereof) if Landlord has adequate space available in the Building for a comparable term, or (B) for a period of one hundred eighty (180) days following the submission of a written proposal for the lease of space (and thereafter if a mutual agreement such as a letter of intent is executed within such period), any other person or entity with which Landlord is in the process of negotiating for the rental of space in the Building; or (vii) either such assignment or sublease or any consideration payable to Landlord in connection therewith adversely affects the real estate investment trust qualification tests applicable to Landlord or Landlord’s Representatives pursuant to Section 856(c) of the Internal Revenue Code of 1986, as amended from time to time. Any attempted assignment, transfer or other encumbrance of this Lease or all or any of Tenant’s rights hereunder or interest herein, and any sublet or permission to use or occupy the Premises or any part thereof not in accordance with this Article VII, shall, at Landlord’s election, be void and of no force or effect. Any assignment or subletting, Landlord’s consent thereto, the listing or posting of any name other than Tenant’s, or Landlord’s collection or acceptance of rent from any assignee or subtenant shall not be construed either (x) as waiving or releasing Tenant from any of its liabilities or obligations under this Lease as a principal and not as a guarantor or surety, for all of which liabilities and obligations Tenant shall remain fully liable hereunder, or (y) as relieving Tenant or any assignee or subtenant from the obligation of obtaining Landlord’s prior written consent to any subsequent assignment or subletting. As security for this Lease, Tenant hereby assigns to Landlord the rent due from any assignee or subtenant of Tenant. During any period that there exists an uncured Event of Default under this Lease, Tenant hereby authorizes each such assignee or subtenant to pay said rent directly to Landlord upon receipt of notice from Landlord specifying same. Landlord’s collection of such rent shall not be construed as an

acceptance of such assignee or subtenant as a tenant. Tenant shall not mortgage, pledge, hypothecate or encumber (collectively "**mortgage**") this Lease. Tenant shall pay to Landlord an administrative fee equal to five hundred dollars (\$500) plus all other reasonable, out-of-pocket, third party expenses (including reasonable attorneys' fees and accounting costs) incurred by Landlord in connection with Tenant's request for Landlord to give its consent to any assignment, subletting, or mortgage, and Landlord's receipt of such sum shall be a condition to Landlord providing such consent. Any sublease, assignment or mortgage shall, at Landlord's option, be effected on forms reasonably approved by Landlord. Tenant shall deliver to Landlord a fully executed copy of each agreement evidencing a sublease, assignment or mortgage, and Landlord's consent thereto, within ten (10) days after execution thereof.

7.2 (a) If Tenant is or becomes a partnership or a limited liability company, then any event (whether voluntary, concurrent or related) resulting in a dissolution of Tenant, any withdrawal or change (whether voluntary, involuntary or by operation of law) of the partners or members, as applicable, owning a controlling interest in Tenant (including each general partner or manager, as applicable), or any structural or other change having the effect of limiting the liability of the partners shall be deemed a prohibited assignment of this Lease subject to the provisions of this Article. If Tenant is or becomes a corporation or a partnership with a corporate general partner, then any event (whether voluntary, concurrent or related) resulting in a dissolution, merger, consolidation or other reorganization of Tenant (or such corporate general partner), or the sale or transfer or relinquishment of the interest of shareholders who, as of the date of this Lease, own a controlling interest of the capital stock of Tenant (or such corporate general partner), shall be deemed a prohibited assignment of this Lease subject to the provisions of this Article; provided, however, that if Tenant is a corporation whose stock is traded through a national or regional exchange or over the counter market, then the foregoing portion of this sentence shall be applicable only if such event has or is intended to have the effect of limiting liability under this Lease.

(b) Notwithstanding anything contained in this Article VII to the contrary, provided no Event of Default exists hereunder, Tenant may, upon not less than ten (10) days' prior written notice to Landlord (which notice shall contain a written certificate from Tenant signed by an authorized representative of Tenant, containing a representation as to the true, correct and complete legal and beneficial relationship of Tenant and the proposed assignee, transferee or subtenant) but without Landlord's prior written consent and without being subject to Landlord's rights and Tenant's obligations set forth in Sections 7.4 and 7.5 below, assign or transfer its entire interest in this Lease or sublease the entire or any portion of the Premises to an Affiliate of Tenant. In the event of any such assignment or subletting, Tenant shall remain fully liable as a primary obligor for the payment of all rent and other charges required hereunder and for the performance of all obligations to be performed by Tenant hereunder. Notwithstanding the foregoing, if Tenant structures an assignment or sublease to an entity that meets the definition of an Affiliate of Tenant for the purpose of circumventing the restrictions on subleases and assignments provided elsewhere in this Article VII, then such subtenant or assignee shall conclusively be deemed not to be an Affiliate of Tenant and subject to all such restrictions.

7.3 If at any time during the Lease Term Tenant desires to assign or sublet all or part of this Lease or the Premises and the same is subject to Landlord's consent, then in connection with Tenant's request to Landlord for Landlord's consent where required, Tenant shall give to Landlord a Tenant's Sublease Request Notice, which shall specify the Proposed Sublet Space and the Proposed Sublet Term, evidence of financial responsibility of such proposed assignee, subtenant or other party in light of the financial obligation being assigned to such party, and a certification executed by Tenant and such party stating whether or not any premium or other consideration is being paid for the assignment, sublease or other transaction.

7.4 Except as set forth in Section 7.2(b) concerning Affiliates, Landlord shall have the right in its sole and absolute discretion to terminate this Lease with respect to the Proposed Sublet Space for the Proposed Sublet Term by sending Tenant written notice of such termination within thirty (30) days after Landlord's receipt of Tenant's Sublease Request Notice. If the Proposed Sublet Space does not constitute the entire Premises and/or if the Proposed Sublet Term does not constitute the entire remaining term hereof, and if Landlord so terminates, then (a) Tenant shall tender the Proposed Sublet Space to Landlord on the Proposed Sublease Commencement Date and such space shall thereafter be deleted from the Premises for the Proposed Sublet Term, and (b) as to that portion of the Premises (if any) which is not part of the Proposed Sublet Space, this Lease shall remain in full force and effect except that Base Rent and additional rent shall be reduced pro rata, and (c) if applicable, as of the expiration of the Proposed Sublet Term, Landlord shall return the Proposed Sublet Space to Tenant in its then as-is condition for the remainder of the term hereof. Tenant shall perform, at its expense, any and all construction and other work required to permit the operation of the Proposed Sublet Space separate from the balance of the Premises, or Landlord may at its option perform such work, in which event Tenant shall pay to Landlord as additional rent the costs and expenses incurred by Landlord in connection therewith. If the Proposed Sublet Space constitutes the entire Premises and the Proposed Sublet Term constitutes the entire remaining term hereof, and Landlord so terminates, then Tenant shall tender the Proposed Sublet Space to Landlord, and this Lease shall terminate, on the Proposed Sublease Commencement Date.

7.5 If any sublease or assignment (whether by operation of law or otherwise, including an assignment pursuant to the Bankruptcy Code or any Insolvency Law) provides that the subtenant or assignee thereunder is to pay any amount in excess of the sum of (a) the rent and other charges due under this Lease plus (b) the reasonable out-of-pocket expenses (excluding, however, any costs attributable to vacancy periods or "downtime") reasonably incurred by Tenant in connection with the procurement of such sublease, assignment or other transfer (which expenses shall be amortized on a straight-line basis over the initial sublease term for the purposes hereof), then, whether such net excess be in the form of an increased monthly or annual rental, a lump sum payment, payment for the sale, transfer or lease of Tenant's fixtures, leasehold improvements, furniture and other personal property, or any other form of payment having the effect of a "disguised" rental payment (and if the subleased or assigned space does not constitute the entire Premises, the existence of such excess shall be determined on a pro rata basis), Tenant shall pay to Landlord, along with Base Rent, fifty percent (50%) of any such net excess or other premium, which amount shall be calculated and paid by Tenant to Landlord on a monthly basis as additional rent. Notwithstanding the foregoing, Landlord is not intending to receive any amounts considered to be based on the net income or profits of Tenant or any subtenant. Acceptance by Landlord of any payments due under this Section shall not be deemed to constitute approval by Landlord of any sublease or assignment, nor shall such acceptance waive any rights of Landlord hereunder. Landlord shall have the right to inspect and audit Tenant's books and records relating to any sublease or assignment.

7.6 All restrictions and obligations imposed pursuant to this Lease on Tenant shall be deemed to extend to any subtenant, assignee, licensee, concessionaire or other occupant or transferee (provided that Landlord's consent to any further assignments of the Lease or further sublet of any portion of the Premises shall be at Landlord's sole and absolute discretion), and Tenant shall cause such person to comply with such restrictions and obligations. Any assignee shall be deemed to have assumed obligations as if such assignee had originally executed this Lease and at Landlord's request shall execute promptly a document confirming such assumption. Each sublease is subject to the condition that if the Lease Term is terminated or Landlord succeeds to Tenant's interest in the Premises by voluntary surrender or otherwise, at Landlord's option the subtenant shall be bound to Landlord for the balance of the term of such sublease and shall attorn to and recognize Landlord as its landlord under the then executory terms of such sublease.

7.7 Notwithstanding anything to the contrary in this Lease, if Tenant or any proposed subtenant or assignee claims that Landlord has unreasonably withheld or delayed its consent or otherwise has breached or acted unreasonably under this Article VII, the sole remedies shall be a suit for contract damages (other than damages for injury to, or interference with, Tenant's business including, without limitation, loss of profits, however occurring) or a declaratory judgment and an injunction for the relief sought, and Tenant hereby waives the provisions of any statute, and all other remedies, including, without limitation, any right at law or equity to terminate this Lease, on its own behalf and, to the extent permitted under all applicable Laws, on behalf of the proposed subtenant or assignee.

ARTICLE VIII
MAINTENANCE AND REPAIRS

8.1 Tenant, at Tenant's sole cost and expense, shall promptly make all repairs and replacements, and perform all maintenance, in and to the Premises to keep the Premises in good operating condition and repair, in a clean, safe and tenantable condition, and otherwise in accordance with all Laws and the requirements of this Lease. Tenant shall likewise maintain all fixtures, furnishings and equipment located in, or exclusively serving, the Premises and make all required repairs and replacements thereto. Tenant shall also maintain, repair and replace, at Tenant's sole cost and expense, the Tenant Items and shall keep in force customary maintenance and service contracts therefor. Tenant shall give Landlord prompt written notice of any defects or damage to the structure of, or equipment or fixtures in, the Building or any part thereof, or any mold or moisture condition, of which Tenant has knowledge. Tenant shall suffer no waste or injury to any part of the Premises, and shall, at the expiration or earlier termination of the Lease Term, surrender the Premises broom clean, and in a good order and condition equal to or better than that on the Lease Commencement Date, except for ordinary wear and tear and as otherwise provided in Article XIII or Article XVII. Except as otherwise provided in Article XVII, all injury, breakage and damage to the Premises and to any other part of the Building or the Land caused by any act or omission of Tenant or any Agent of Tenant, shall be repaired by and at Tenant's expense, except that if either an emergency condition exists or the Lease Term has

expired or Tenant fails to commence and diligently prosecute to completion repair of any such injury, breakage or damage within a reasonable period (not to exceed ten (10) days) following Tenant's receipt of notice from Landlord, then Landlord shall have the right at Landlord's option to make any such repair and to charge Tenant for all costs and expenses incurred in connection therewith, together with Landlord's standard administrative fee. Landlord shall provide and install replacement tubes for Building standard fluorescent light fixtures (subject to reimbursement pursuant to Article V). All other bulbs and tubes for the Premises shall be provided and installed at Tenant's expense (including Landlord's standard administrative fee); provided that if Tenant elects to supply the bulbs or tubes to Landlord, then Landlord shall provide the labor involved for such replacement at Tenant's expense (including Landlord's standard administrative fee).

8.2 Except as otherwise provided in this Lease and subject to normal wear and tear, Landlord at its expense (subject to reimbursement pursuant to Article V if and to the extent permitted thereby) shall keep the Common Areas and the Building Structure and Systems, clean and in good operating condition and, promptly after becoming aware of any item needing repair or replacement, will make such repair or replacement. Notwithstanding any of the foregoing to the contrary: (a) maintenance and repair of all Tenant Items shall be the sole responsibility of Tenant and shall be deemed not to be a part of the Building Structure and Systems; and (b) Landlord shall have no obligation to make any repairs whatsoever brought about by any act or omission of Tenant or any Agent of Tenant. To the fullest extent permitted by Law, Tenant hereby waives all rights to make repairs at the expense of Landlord or in lieu thereof to vacate the Premises as may be provided by any Law. Landlord has no obligation and has made no promise to alter, remodel, improve, repair, decorate or paint the Premises or any part thereof, except as specifically and expressly herein set forth.

ARTICLE IX **ALTERATIONS**

9.1 Tenant shall accept the Premises in its "as is" condition as of the Lease Commencement Date; provided, however, Landlord shall paint the Premises in a building standard paint color and clean the existing laminate floors in the Premises prior to delivery of the Premises to Tenant. Except as expressly set forth in this Section 9.1, Landlord is under no obligation to make any Alterations in or to the Premises or the Building.

9.2 Tenant shall not make or permit anyone to make any Alterations in or to the Premises or the Building without the prior written consent of Landlord, which consent may be withheld or granted in Landlord's sole and absolute discretion with respect to Structural and System Alterations and any Alterations which are visible from the exterior of the Premises, and which consent shall not be unreasonably withheld, conditioned or delayed with respect to all other Alterations. Notwithstanding the foregoing, Tenant shall have the right to make Cosmetic Changes within the Premises without first obtaining the consent of Landlord. All Alterations made by Tenant shall be made: (a) in a good, workerlike, first class and prompt manner; (b) using new or comparable materials only; (c) by a contractor reasonably approved in writing by Landlord; (d) on days and at times reasonably approved in writing by Landlord; (e) if architectural and/or engineering plans are required for such Alterations, under the supervision of

an architect reasonably approved in writing by Landlord; (f) in accordance with plans and specifications reasonably acceptable to Landlord, approved in writing at Landlord's standard charge; (g) in accordance with all Laws, this Lease, and Landlord's then-current construction rules and regulations; (h) after Tenant and its contractors have complied with the insurance requirements set forth in this Lease, and any additional insurance to be obtained by Tenant's contractors and subcontractors as reasonably required by Landlord; and (i) upon request, after Tenant has delivered to Landlord documentation reasonably satisfactory to Landlord evidencing Tenant's financial ability to complete the Alterations in accordance with the provisions of this Lease (including, at Landlord's reasonable request, a payment or performance bond). If any lien (or a petition to establish such lien) is filed in connection with any Alteration made by or on behalf of Tenant, such lien (or petition) shall be discharged by Tenant within ten (10) days thereafter, at Tenant's sole cost and expense, by the payment thereof or by the filing of a bond reasonably acceptable to Landlord. If Landlord gives its consent to the making of any Alteration, such consent shall not be deemed to be an agreement or consent by Landlord to subject its interest in the Premises or the Building to any liens which may be filed in connection therewith. Tenant acknowledges that any Alterations are accomplished for Tenant's account and at Tenant's sole cost and expense, Landlord having no obligation or responsibility in respect thereof. Landlord's approval of any plans and drawings (and changes thereto) regarding any Alterations or any contractor or subcontractor performing such Alterations shall not constitute Landlord's representation that such approved plans, drawings, changes or Alterations comply with Laws. Any deficiency in design or construction, although same had prior approval of Landlord, shall be solely the responsibility of Tenant. All Alterations involving structural, electrical, mechanical or plumbing work, the heating, ventilation and air conditioning system of the Premises or the Building, fire and life safety systems, the roof of the Building, or any areas outside of the Premises shall, at Landlord's election, be performed by Landlord's designated contractor or subcontractor at Tenant's expense (provided the cost therefor is competitive). In connection with any Alteration, Landlord shall be paid a construction supervision fee in an amount equal to five percent (5%) of the total cost of such Alteration. Promptly after the completion of an Alteration for which architectural and/or engineering plans were required, or which includes Cabling, Tenant at its expense shall deliver to Landlord three (3) sets of accurate as built (or record) drawings and CAD drawings showing such Alteration in place. In addition, on Landlord's request, Tenant shall certify the names of all contractors and subcontractors who did work on the Alterations and shall provide final lien waivers from all such contractors and subcontractors and any other documentation customarily provided in the State in which the Building is located to extinguish liens. All contractors and subcontractors shall be required to procure and maintain insurance against such risks, in such amounts, and with such companies as Landlord may reasonably require. Certificates of such insurance, with evidence of the payment of premiums therefor, must be received by Landlord before any work is commenced. All contracts between Tenant and a contractor must explicitly require the contractor to (a) name Landlord and the Landlord Insured Parties as additional insureds and (b) indemnify and hold harmless Landlord and the Landlord Insured Parties. Notwithstanding anything contained in this Lease to the contrary, the performance of any Alterations pursuant to the provisions of this Article IX or of any other provisions of this Lease or the Exhibits hereto shall not be done in a manner which would violate any union contracts affecting the Building, or by which Landlord is bound, or create any work stoppage, picketing, labor disruption, disharmony or dispute or any interference with the business of Landlord or any tenant or occupant of the Building. Tenant

shall immediately stop the performance of any Alterations or other activity if Landlord notifies Tenant that continuing such Alteration or activity would violate any union contracts affecting the Building, or by which Landlord is bound, or create any work stoppage, picketing, labor disruption, disharmony or dispute or any interference with the business of Landlord or any tenant or occupant of the Building.

9.3 If any Alterations that require Landlord's consent are made without the prior written consent of Landlord, then Landlord shall have the right, at Tenant's expense, to remove such Alterations and restore the Premises and the Building to their condition prior to the commencement of the unauthorized Alterations. All Alterations to the Premises or the Building made by either party shall immediately become the property of Landlord and shall remain upon and be surrendered with the Premises as a part thereof at the expiration or earlier termination of the Lease Term; provided, however, that (a) subject to any applicable Landlord's lien thereon, Tenant shall remove from the Premises, prior to the expiration or earlier termination of the Lease Term, (i) all personal property of Tenant, including without limitation movable furniture, furnishings and equipment installed in the Premises solely at the expense of Tenant ("**Personal Property**"), and (ii) all Cabling installed by or for Tenant anywhere in the Building, and (b) Tenant shall remove at its expense all Alterations and other items in the Premises or the Building which Landlord designates in writing for removal. Landlord shall make such designation promptly after receipt of a written request for such determination by Tenant given with Tenant's request for Landlord's approval of such Alteration. Notwithstanding the foregoing, Tenant shall not be required to remove: (x) Alterations (other than Cabling) consisting of standard buildout items that are typically installed by similar tenants in multi tenanted, multi-story, first class office buildings (such as partitions, but not interior staircases, for example), unless so indicated by Landlord at the time required above; and (y) any Alteration made by Tenant in initially finishing and completing the Premises, except any Structural and System Alterations or as otherwise indicated on Landlord's approval of any of Tenant's plans. If such removal causes damage or injury to the Premises or the Building, then Landlord shall have the right, at Tenant's expense, to repair all damage and injury to the Premises or the Building caused by such removal as aforesaid. Tenant expressly agrees that if any of Tenant's Personal Property is not removed by Tenant prior to the earlier of (i) the expiration (or earlier termination) of the Lease Term or (ii) the termination of Tenant's right of possession of the Premises, the same shall, at Landlord's option, be deemed abandoned or become the property of Landlord surrendered with the Premises as a part thereof; provided, however, that Landlord shall have the right at Tenant's expense to remove from the Premises any or all such items or to require Tenant to do the same, except as otherwise provided in this Section. If Tenant fails to return the Premises to Landlord as required by this Section, then Tenant shall pay to Landlord, all costs (including a construction management fee) incurred by Landlord in effectuating such return.

9.4 Landlord and Tenant acknowledge and agree that the Premises shall be delivered by Landlord with certain fixtures, furniture, and equipment, as more particularly described in **Exhibit B** (the "**FF&E**"). Landlord has agreed to permit Tenant the use of such FF&E pursuant to this Section 9.4:

(a) Landlord has made no representations or warranties whatsoever as to the condition of the FF&E or Landlord's title thereto (other than that Landlord has the power and authority to permit Tenant to use the FF&E as provided in this Section 9.4);

(b) Tenant has examined the FF&E and accepts same in its "as-is, where-is" condition in all respects;

(c) Throughout the Lease Term (including any renewals or extensions thereof), Tenant may use the FF&E for their intended purposes without charge;

(d) Tenant shall not sell, transfer or remove from the Premises, any portion of the FF&E;

(e) Base Rent and Additional Rent payable by Tenant pursuant to this Lease, does not include any charge whatsoever for Tenant's use of the FF&E. Accordingly, if all or any portion of the FF&E is removed from the Premises or is otherwise no longer available for use by Tenant, there shall not be a reduction in or abatement of the Base Rent or the Additional Rent payable by Tenant hereunder;

(f) Throughout the Lease Term (as it may be extended or renewed), Tenant shall, at its sole cost and expense, (i) repair and maintain the FF&E in the same condition as originally received (except for ordinary wear and tear) and (ii) cause the FF&E to be insured in the same manner as required under this Lease for Tenant's personal property (except that Landlord shall be named as an additional insured with respect thereto);

(g) Tenant shall neither replace any of the FF&E nor add any improvements to or otherwise modify the FF&E, without Landlord's prior, written approval. Tenant shall make all approved replacements, improvements and/or modifications at its sole cost and expense; and

(h) Upon the expiration or sooner termination of this Lease or of Tenant's right to possession of the Premises, Tenant shall return the FF&E, and all replacements, improvements and/or modifications thereto, if any, to Landlord in the same order and condition as originally received by Tenant (normal wear and tear and approved replacements, improvements and/or modifications excepted).

ARTICLE X

SIGNS

10.1 Landlord will, in connection with Tenant's initial occupancy of the Premises and at Landlord's expense, (i) list the name of Tenant in the Building lobby directory, if any, based on Tenant's pro-rata share of rentable square feet leased in the Building, and (ii) provide Building standard suite entry signage next to one suite entry door, and directional signage in the elevator lobby on the seventh (7th) floor of the Building. Tenant shall not place, inscribe, paint, affix or otherwise display any sign, advertisement, picture, lettering or notice of any kind on any part of the exterior or interior of the Building (including windows and doors), or on any part of the interior of the Premises which can be seen from outside the Premises, without the prior written approval of Landlord, which may be granted or withheld in Landlord's sole and absolute

discretion. Notwithstanding the foregoing, Tenant shall have the right, subject to Landlord's consent, not to be unreasonably withheld, conditioned or delayed, to place its signage on the door to the Premises, at its sole cost and expense. If any such item that has not been approved by Landlord is so displayed, then Landlord shall have the right to remove such item at Tenant's expense. Landlord reserves the right to install and display signs, advertisements and notices on any part of the exterior or interior of the Building; provided, however that Landlord shall not affix, install, or display signs on the interior of the Premises, except as may be required by Law.

ARTICLE XI
SECURITY DEPOSIT

11.1 Simultaneously with Tenant's execution of this Lease, Tenant shall deposit with Landlord the Security Deposit Amount as a security deposit for the performance by Tenant of all of Tenant's obligations, covenants, conditions and agreements under this Lease. Landlord shall not be required to maintain such security deposit in a separate account. Tenant shall not be entitled to interest on the security deposit. Within thirty (30) days after the later of the expiration or earlier termination of the Lease Term or Tenant's vacating the Premises, Landlord shall return such security deposit to Tenant, less such portion thereof as Landlord shall have appropriated to satisfy any of Tenant's obligations under this Lease or to satisfy an Event of Default (or such other event which, with the giving of notice or the passage of time or both, would constitute an Event of Default) under this Lease, and subject to retention of such amount as Landlord may determine to be appropriate to secure payment of any rentals or charges or adjustments thereof which may become due following expiration or termination. If Tenant fails to pay rent or other charges due hereunder, or otherwise defaults with respect to any provision of this Lease, Landlord shall have the right, but shall not be obligated, to use, apply or retain all or any portion of the Security Deposit for the payment of any rent or other charge in default or for the payment of any other sum to which Landlord may become obligated by reason of Tenant's default, to repair damages to the Premises caused by Tenant, to clean the Premises upon expiration or termination, or to compensate Landlord for any loss or damage which Landlord may suffer thereby, including, but not limited to, damages recoverable following termination of this Lease by reason of an Event of Default as herein provided, and any and all amounts Landlord may spend or become obligated to spend, or for the compensation of Landlord for any losses incurred, by reason of such event. If any portion of the security deposit (in whatever form) is so used or applied, then within five (5) business days after Landlord gives written notice to Tenant of such use or application, Tenant shall deposit with Landlord cash in an amount sufficient to restore the security deposit to the original Security Deposit Amount, and Tenant's failure to do so shall constitute an Event of Default under this Lease.

11.2 If and so long as Landlord transfers the security deposit to any purchaser or other transferee of Landlord's interest in the Building, then Tenant shall look only to such purchaser or transferee for the return of the security deposit, and Landlord shall be released from all liability to Tenant for the return of such security deposit. Tenant acknowledges that the holder of any Mortgage shall not be liable for the return of any security deposit made by Tenant hereunder unless such holder actually receives such security deposit. Tenant shall not pledge, mortgage, assign or transfer the security deposit or any interest therein.

11.3 At Landlord's option, in Landlord's sole and absolute discretion, Tenant shall deliver to Landlord a clean, unconditional, irrevocable letter of credit in lieu of the cash security deposit. Such letter of credit shall be: (a) in form and substance satisfactory to Landlord in its sole and absolute discretion (with the following criteria at a minimum); (b) at all times in the stated face amount of not less than the Security Deposit Amount, and shall on its face state that multiple and partial draws are permitted and either (i) that partial draws will not cause a corresponding reduction in the stated face amount of the letter of credit or (ii) that, within five (5) business days after any such partial draw, the issuer will notify Landlord in writing that the letter of credit will not be reinstated to its full amount in which event Landlord shall have the right to immediately draw on the remainder of the letter of credit (it being understood that the total security deposit on hand, whether in cash or letter of credit form, shall at all times be not less than the total Security Deposit Amount as so defined); (c) issued by a commercial bank acceptable to Landlord from time to time and located in the Boston metropolitan area for the account of Tenant, and its permitted successors and assigns under this Lease; (d) made payable to, and expressly transferable and assignable one or more times at no charge by, the owner from time to time of the Building or its lender (which transfer/assignment shall be conditioned only upon the execution of a reasonable and customary written document in connection therewith), whether or not the original account party of the letter of credit continues to be the tenant under this Lease by virtue of a change in name or structure, merger, assignment, transfer or otherwise; (e) payable at sight upon presentment to a Boston metropolitan area branch of the issuer of a simple sight draft stating only that Landlord is permitted to draw on the letter of credit under the terms of the Lease and setting forth the amount that Landlord is drawing; (f) of a term not less than one year, and shall on its face state that the same shall be renewed automatically, without the need for any further written notice or amendment, for successive minimum one year periods, unless the issuer notifies Landlord in writing, at least sixty (60) days prior to the expiration date thereof, that such issuer has elected not to renew the letter of credit (which will thereafter entitle Landlord to draw on the letter of credit); and (g) at least thirty (30) days prior to the then current expiration date of such letter of credit, either (1) renewed (or automatically and unconditionally extended) from time to time through the ninetieth (90th) day after the expiration of the Lease Term, or (2) replaced by Tenant with cash, or another letter of credit meeting the requirements of this Section, in the full amount of the Security Deposit Amount. Tenant shall cooperate with Landlord to effect any modifications, transfers or replacements of the letter of credit requested by Landlord in order to assure that Landlord is at all times fully secured by a valid letter of credit that may be drawn upon by Landlord, its successors and assigns. Notwithstanding anything in this Lease to the contrary, any cure or grace period provided in connection with an Event of Default shall not apply to any of the foregoing requirements of the letter of credit, and, specifically, if any of the aforesaid requirements are not complied with timely, then an immediate Event of Default shall occur and Landlord shall have the right to immediately draw upon the letter of credit without notice to Tenant and apply the proceeds to the security deposit. Each letter of credit shall be issued by a commercial bank that has a credit rating with respect to certificates of deposit, short term deposits or commercial paper of at least A-2 (or equivalent) by Moody's Investors Service, Inc., or at least P-2 (or equivalent) by Standard & Poor's Corporation, and shall be otherwise acceptable to Landlord in its sole and absolute discretion. If the issuer's credit rating is reduced below A-2 (or equivalent) by Moody's Investors Service, Inc. or below P-2 (or equivalent) by Standard & Poor's Corporation, or if the financial condition of such issuer changes in any other materially adverse way, then Landlord shall have the right to

require that Tenant obtain from a different issuer a substitute letter of credit that complies in all respects with the requirements of this Section, and Tenant's failure to obtain such substitute letter of credit within ten (10) days following Landlord's written demand therefor (with no other notice or cure or grace period being applicable thereto, notwithstanding anything in this Lease to the contrary) shall entitle Landlord to immediately draw upon the then existing letter of credit in whole or in part, without notice to Tenant. In the event the issuer of any letter of credit held by Landlord is insolvent or is placed into receivership or conservatorship by the Federal Deposit Insurance Corporation, or any successor or similar entity, or if a trustee, receiver or liquidator is appointed for the issuer, then, effective as of the date of such occurrence, said letter of credit shall be deemed to not meet the requirements of this Section, and, within ten (10) days thereof, Tenant shall replace such letter of credit with other collateral acceptable to Landlord in its sole and absolute discretion (and Tenant's failure to do so shall, notwithstanding anything in this Lease to the contrary, constitute an Event of Default for which there shall be no notice or grace or cure periods being applicable thereto other than the aforesaid ten (10) day period). Any failure or refusal of the issuer to honor the letter of credit shall be at Tenant's sole risk and shall not relieve Tenant of its obligations hereunder with respect to the security deposit.

ARTICLE XII
INSPECTION

12.1 Tenant shall permit Landlord, its agents and representatives, and the holder of any Mortgage, to enter the Premises at any time and from time to time, without charge therefor and without diminution of the rent payable by Tenant, in order to examine, inspect or protect the Premises and the Building, to make such alterations and/or repairs as in the sole but reasonable judgment of Landlord may be deemed necessary or desirable, or to exhibit the same to brokers, prospective tenants (during the last twelve (12) months of the Lease Term), lenders, purchasers and others. Except in the event of an emergency, Landlord shall endeavor: to give Tenant reasonable advance notice (which may be oral or email notice to Tenant's office manager at the Premises) of any such entry and to permit Tenant to have a representative present at such time; and to minimize disruption to Tenant's normal business operations in the Premises in connection with any such entry (but same shall not prohibit Landlord from performing maintenance and repairs during business hours and that Landlord shall have no obligation to employ overtime or other premium pay labor or other costs in connection therewith).

ARTICLE XIII
INSURANCE

13.1 Tenant shall not conduct or permit to be conducted any activity, or place or permit to be placed any equipment or other item in or about the Premises or the Building which will in any way increase the rate of property insurance or other insurance on the Building. If any increase in the rate of property or other insurance is due to any activity, equipment or other item of Tenant, then (whether or not Landlord has consented to such activity, equipment or other item) Tenant shall pay as additional rent due hereunder the amount of such increase. The statement of any applicable insurance company or insurance rating organization (or other organization exercising similar functions in connection with the prevention of fire or the correction of hazardous conditions) that an increase is due to any such activity, equipment or other item shall be conclusive evidence thereof.

13.2 (a) Throughout the Lease Term, Tenant shall obtain and maintain the following insurance coverages written with companies with an A.M. Best A-, X or better rating and S&P rating of at least A-:

(i) Commercial General Liability (“**CGL**”) insurance (written on an occurrence basis) with limits not less than One Million Dollars (\$1,000,000) combined single limit per occurrence, Two Million Dollar (\$2,000,000) annual general aggregate (on a per location basis), Two Million Dollars (\$2,000,000) products/completed operations aggregate, One Million Dollars (\$1,000,000) personal and advertising injury liability, Fifty Thousand Dollars (\$50,000) fire damage legal liability, and Five Thousand Dollars (\$5,000) medical payments. CGL insurance shall be written on a current ISO occurrence form CG 00 01 96 (or a substitute form providing equivalent or broader coverage) and shall cover liability arising from Premises, operations, independent contractors, products-completed operations, personal injury, advertising injury and liability assumed under an insured contract.

(ii) Workers Compensation insurance as required by the applicable state law, and Employers Liability insurance with limits not less than One Million Dollars (\$1,000,000) for each accident, One Million Dollars (\$1,000,000) disease policy limit, and One Million Dollars (\$1,000,000) disease each employee.

(iii) Commercial Auto Liability insurance (“**Auto Policy**”) (if applicable) covering automobiles owned, hired or used by Tenant in carrying on its business with limits not less than One Million Dollars (\$1,000,000) combined single limit for each accident.

(iv) Umbrella/Excess Insurance (“**Umbrella**”) coverage on a follow form basis in excess of the CGL, Employers Liability and Auto Policy with limits not less than Five Million Dollars (\$5,000,000) per occurrence and Five Million Dollars (\$5,000,000) annual aggregate.

(v) All-Risk Property Insurance (“**Property Policy**”) covering Tenant’s property, furniture, furnishings, fixtures, improvements and equipment located at the Building. If Tenant is responsible for any machinery, Tenant shall maintain boiler and machinery insurance.

(vi) Business Interruption and Extra Expenses insurance in amounts typically carried by prudent tenants engaged in similar operations, but in no event in an amount less than double the annual Base Rent and additional rent then in effect during any Lease Year. Such insurance shall reimburse Tenant for direct and indirect loss of earnings and extra expense attributable to all perils insured against.

(vii) Builder's Risk (or Building Constructions) insurance during the course of construction of any Alteration by Tenant. Such insurance shall be on a form covering Landlord, Landlord's architects, Landlord's contractor or subcontractors, Tenant and Tenant's contractors, as their interest may appear, against loss or damage by fire, vandalism, and malicious mischief and other such risks as are customarily covered by the so-called "broad form extended coverage endorsement" upon all Alterations in place and all materials stored at the Premises, and all materials, equipment, supplies and temporary structures of all kinds incident to Alterations and builder's machinery, tools and equipment, all while forming a part of, or on the Premises, or when adjacent thereto, while on drives, sidewalks, streets or alleys, all on a completed value basis for the full insurable value at all times. Said Builder's Risk Insurance shall contain an express waiver of any right of subrogation by the insurer against Landlord, its agents, employees and contractors.

(b) Landlord and the Landlord Insured Parties shall be endorsed on each policy as additional insureds as it pertains to the CGL, Umbrella, and Auto Policy, and coverage shall be primary and noncontributory. Landlord shall be a loss payee on the Property Policy in respect of Tenant's improvements to the extent that Landlord is responsible for the repair and replacement of same under Article XVII. All insurance shall (1) contain an endorsement that such policy shall remain in full force and effect notwithstanding that the insured may have waived its right of action against any party prior to the occurrence of a loss; (2) provide that the insurer thereunder waives all right of recovery by way of subrogation against Landlord and Landlord's Representatives in connection with any loss or damage covered by such policy (and Tenant shall provide evidence of such waiver); and (3) be acceptable in form and content to Landlord. Tenant shall cause its insurance carrier to provide Landlord with thirty (30) days' advance notice (ten (10) days' for non-payment of premium) of any cancellation, failure to renew, reduction of amount of insurance or change in Tenant's insurance coverage if it is reasonable and customary for an office tenant in the Building's submarket to obtain such an undertaking from its insurance carrier. In the event Tenant's insurance carrier will not agree to provide Landlord advance notice as aforesaid, then Tenant shall give Landlord notice of cancellation, failure to renew, reduction of amount of insurance, or change of Tenant's insurance coverage no later than two (2) business days after Tenant learns of such cancellation, failure to renew, reduction of amount of insurance, or change of coverage. Any such policy may provide for a commercially reasonable deductible. Landlord reserves the right from time to time to reasonably require higher minimum amounts or different types of insurance. Tenant shall deliver an ACORD 25 certificate or its equivalent with respect to all liability and personal property insurance and an ACORD 28 certificate or its equivalent with respect to all commercial property insurance and receipts evidencing payment therefor (and, upon request, copies of all required insurance policies, including endorsements and declarations) to Landlord on or before delivery of possession of the Premises to Tenant and at least annually thereafter. If Tenant fails to provide evidence of insurance required to be provided by Tenant hereunder, prior to commencement of the Lease Term and thereafter within thirty (30) days following Landlord's request during the Lease Term (and in any event within thirty (30) days prior to the expiration date of any such coverage, any other cure or grace period provided in this Lease not being applicable hereto), Landlord shall be authorized (but not required) after ten (10) days' prior notice to procure such coverage in the amount stated with all costs thereof to be chargeable to Tenant and payable as additional rent upon written invoice therefor.

13.3 Landlord agrees to carry and maintain special form property insurance (with replacement cost coverage) covering the Building and Landlord's property therein in an amount required by its insurance company to avoid the application of any coinsurance provision. Landlord hereby waives its right of recovery against Tenant and releases Tenant from any and all liabilities, claims and losses for which Tenant may otherwise be liable to the extent Landlord receives proceeds from its property insurance therefor. Landlord shall secure a waiver of subrogation endorsement from its insurance carrier. Landlord also agrees to carry and maintain commercial general liability insurance in limits it reasonably deems appropriate (but in no event less than the limits required by Tenant pursuant to Section 13.2). Landlord may elect to carry such other additional insurance or higher limits as it reasonably deems appropriate. Tenant acknowledges that Landlord shall not carry insurance on, and shall not be responsible for damage to, Tenant's personal property or any Alterations, and that Landlord shall not carry insurance against, or be responsible for any loss suffered by Tenant due to, interruption of Tenant's business.

13.4 Landlord and Tenant hereby waive and shall cause their respective insurance carriers to waive any and all rights of recovery, claims, actions or causes of action against the other for any loss or damage with respect to loss or damage to any property, which loss or damage is (or would have been, had the insurance required by this Lease been carried) covered by insurance.

ARTICLE XIV **SERVICES AND UTILITIES**

14.1 Landlord shall manage and operate (or cause to be managed and operated) the Building in a manner consistent with comparable class office buildings in the Back Bay submarket of Boston (the "**Comparable Standard**"). From and after the Lease Commencement Date, Landlord will provide to the Premises the services and utilities in accordance with applicable Law and in accordance with the standards set forth below, or, if no standards are specified below, in a manner and at a level consistent with the Comparable Standard: air conditioning and heating during Building Hours as required in Landlord's reasonable judgment, substantially in accordance with the specifications set forth in **Exhibit E** attached hereto; janitorial service to the office portions of the Premises (Landlord not being required to clean any mail rooms, kitchen areas (except that Landlord will clean the floors and counter areas of any kitchen area, and remove trash therefrom) or private restrooms within the Premises) on Monday through Friday; electric power from the utility provider sufficient for customary lighting purposes and normal office use (but not less than five (5) watt per rentable square foot of the Premises connected load, which connected load shall be exclusive of base Building HVAC and other base Building systems); standard hot and cold water in Building standard restrooms and (if applicable) chilled water in Building standard drinking fountains; elevator service (with at least one (1) elevator in operation at all times, except in the event of an emergency); landscaping and snow removal during the seasons they are required; and exterior window cleaning service. Notwithstanding the foregoing, Landlord shall provide Tenant with air conditioning and heating

on Saturdays during Building Hours (excluding Holidays) at no additional cost only upon the request of Tenant. If Tenant requires air conditioning or heat beyond the Building Hours, then Landlord will furnish the same provided Tenant gives Landlord one business day's advance notice of such requirement. Tenant shall pay for such extra service in accordance with Landlord's then-current schedule (currently \$80.00 per hour per floor, subject to adjustment at any time and from time to time without notice, with a one (1) hour usage minimum). To the extent Tenant provides or contracts for any services relating to any Building Structure or System or any service or utility being provided by Landlord to the Premises directly from the supplier (which Tenant shall not be permitted to do without Landlord's prior written consent, which consent shall not be unreasonably withheld conditioned or delayed), Tenant shall enter into and maintain (and provide Landlord with a copy of) a service contract therefor with a contractor licensed to do business in the jurisdiction in which the Building is located and otherwise approved by Landlord. Tenant shall have access to the Building twenty four (24) hours per day each day of the year (except in the event of an emergency). Landlord shall provide a card key (or similar type of) access system to provide access to the Building at times other than Building Hours. A reasonable number of access cards or other means of access shall be provided to Tenant at Lease Term commencement at no cost to Tenant (except that Landlord may charge Tenant for replacement cards). Such access cards shall be issued by Landlord to the specific individuals that are designated by Tenant. Tenant shall not permit anyone, except for Tenant's employees, permitted subtenants and assigns and authorized guests, to enter the Building at times other than the Building Hours. All persons entering or exiting the Building at times other than the normal hours of operation of the Building shall, at Landlord's discretion, be required to sign in and out.

14.2 Landlord has installed a submeter to measure Tenant's actual electricity consumption, and, commencing on the Lease Commencement Date, Tenant shall pay for such consumption at the then-current rates charged by the electric service provider selected and used by Landlord, and a three percent (3%) administrative fee.

14.3 Tenant shall reimburse Landlord for the cost of any excess water, sewer and chiller usage in the Premises. Excess usage shall mean the excess of the estimated usage in the Premises (per square foot of rentable area) during any three (3) month billing period over the average usage (per square foot of rentable area) during the same period for the entire Building, as reasonably calculated by Landlord in good faith.

14.4 Landlord shall not have any liability to Tenant, and Tenant shall not be entitled to terminate this Lease or receive a rent abatement, in the event of Landlord's failure or inability to furnish any of the utilities or services required to be furnished by Landlord hereunder; provided, however, that (a) if Landlord is not proceeding diligently and in good faith to correct such failure or inability, and if all or substantially all of the Premises is rendered unusable by Tenant for a continuous period of seven (7) consecutive business days after Tenant gives Landlord written notice thereof, and if Tenant does not in fact use the Premises during such period, then, so long as no Event of Default exists under this Lease, Tenant shall be entitled, as its sole and exclusive remedy, to an abatement of the Base Rent payable hereunder for the period beginning on the day after such seven (7) business day period ends and continuing until the earlier of the date Tenant resumes use or occupancy of the Premises or the date use of the Premises is restored to Tenant; and (b) Landlord shall use reasonable efforts to restore such failure or inability so long as such failure or inability is within Landlord's reasonable control to correct.

14.5 Tenant acknowledges and agrees that Landlord and Tenant will be subject to certain mandatory informational and other reporting requirements imposed by the City of Boston pursuant to the Building Energy Reporting and Disclosure Ordinance, as the same may be amended from time to time (the "**Energy Reporting Ordinance**") with respect to Tenant's space use attributes and energy use in the Premises and, in connection therewith. Landlord and Tenant shall cooperate with each other in satisfying their respective obligations under the Energy Reporting Ordinance and Tenant shall provide Landlord with copies of Tenant's utility bills and other reasonably requested related information for the prior calendar year not later than February 28th of each calendar year during the Term and such obligation shall survive the expiration or earlier termination of the Term of this Lease with respect to the last Lease Year of the Term.

ARTICLE XV
LIABILITY OF LANDLORD

15.1 Except as otherwise provided in this Article XV, Landlord and Landlord's Representatives shall not be liable to Tenant or any other person or entity for any damage, injury, loss or claim based on or arising out of any cause whatsoever, including the following: repair to any portion of the Premises or the Building; interruption in the use of the Premises or the Building or any equipment therein; any accident or damage resulting from any use or operation (by Landlord, Tenant or any other person or entity) of elevators or heating, cooling, electrical, sewage or plumbing equipment or apparatus; termination of this Lease by reason of damage to the Premises or the Building; any fire, robbery, theft, vandalism, mysterious disappearance or any other casualty; actions of any other tenant of the Building or of any other person or entity; failure or inability to furnish any service specified in this Lease; and leakage in any part of the Premises or the Building from water, rain, ice or snow that may leak into, or flow from, any part of the Premises or the Building, or from drains, pipes or plumbing fixtures in the Premises or the Building. If any condition exists which may be the basis of a claim of constructive eviction, then Tenant shall give Landlord written notice thereof and a reasonable opportunity to correct such condition, and in the interim Tenant shall not claim that it has been constructively evicted or is entitled to a rent abatement. Any property placed by Tenant or any Agent in or about the Premises or the Building shall be at the sole risk of Tenant, and Landlord shall not in any manner be held responsible therefor. Any person receiving an article delivered for Tenant shall be acting as Tenant's agent for such purpose and not as Landlord's agent. For purposes of this Article, the term "Building" shall be deemed to include the Building, the Land and the Parking Facilities. Notwithstanding the foregoing provisions of this Section, Landlord shall not be released from liability to Tenant for any physical injury to any natural person caused by the negligence or willful misconduct of Landlord or Landlord's Representatives to the extent such injury is not covered by insurance either carried by Tenant (or such person) or required by this Lease to be carried by Tenant; provided, however, that neither Landlord nor any of Landlord's Representatives (nor any past, present or future board member, partner, trustee, director, member, officer, employee, agent, representative or advisor of any of them) shall under any circumstances be liable for any exemplary, punitive, consequential or indirect damages (or for any interruption of or loss to business) in connection with or relating to this Lease.

15.2 (a) Except to the extent caused by the negligence or willful misconduct of Landlord or its agents, Tenant shall reimburse Landlord, its employees and agents for (as additional rent), and shall indemnify, defend upon request and hold them harmless from and against all reasonable Costs suffered by or claimed against them, directly or indirectly, based on or arising out of, in whole or in part, (i) use and occupancy of the Premises or the business conducted therein, (ii) any negligent or willful act or omission of Tenant or any Agent of Tenant, (iii) any breach of Tenant's obligations under this Lease, including failure to comply with Laws or surrender the Premises upon the expiration or earlier termination of the Lease Term, or (iv) any entry by Tenant or any Agent of Tenant upon the Land prior to the Lease Commencement Date.

(b) Except to the extent caused by the negligence or willful misconduct of Tenant or an Agent of Tenant, Landlord shall reimburse Tenant and shall indemnify and hold Tenant harmless from and against all Costs suffered or claimed against Tenant as a result of the negligence or willful misconduct of Landlord, its agents, employees or contractors; provided, however, that neither Landlord nor any of Landlord's Representatives (nor any past, present or future board member, partner, trustee, director, member, officer, employee, agent, representative or advisor of any of them) shall under any circumstances be liable for any exemplary, punitive, consequential or indirect damages (or for any interruption of or loss to business) in connection with or relating to this Lease.

15.3 No landlord hereunder shall be liable for any obligation or liability based on or arising out of any event or condition occurring during the period that such landlord was not the owner of any of the Building or the Land, or a landlord's interest therein. Within five (5) days after request, Tenant shall attorn to any transferee landlord and execute, acknowledge and deliver any document submitted to Tenant confirming such attornment provided such transferee assumes the obligations of landlord hereunder which accrue from and after the date of the transfer.

15.4 Tenant shall not have the right to set off or deduct any amount allegedly owed to Tenant pursuant to any claim against Landlord from any rent or other sum payable to Landlord. Tenant's sole remedy for recovering upon such claim shall be to institute an independent action against Landlord, which action shall not be consolidated with any action of Landlord; provided, however, that the foregoing shall not prohibit Tenant from asserting a compulsory counterclaim in any proceeding instituted by Landlord against the Tenant that is required to be brought by applicable statute and will be deemed forever waived if not then asserted by Tenant.

15.5 If Tenant or any Agent is awarded a money judgment against Landlord, then recourse for satisfaction of such judgment shall be limited to execution against Landlord's estate and interest in the Building which shall be deemed to include proceeds actually received by Landlord from any sale of the Building (net of all expenses of sale), insurance or condemnation proceeds (subject to the rights of any holder of any Mortgage), and rental income from the Building (net of all expenses) to the extent all of the foregoing are held in an account for Landlord and have not been applied or distributed by Landlord in the ordinary course of business (i.e., not as a fraud against creditors). No other asset of Landlord, and no asset of any of Landlord's representatives (or any past, present or future board member, partner, director, member, officer, trustee, employee, agent, representative or advisor of any of them (each, an "officer")) or any other person or entity, shall be available to satisfy or be subject to any such judgment. No such Landlord's representative, officer or other person or entity shall be held to have personal liability for satisfaction of any claim or judgment whatsoever under this Lease.

ARTICLE XVI

RULES

16.1 Tenant and its Agents shall at all times abide by and observe the rules specified in **Exhibit C**. Tenant and its Agents shall also abide by and observe any other rule that Landlord may reasonably promulgate from time to time for the operation and maintenance of the Building, provided that written notice thereof is given and such rule is not inconsistent with the provisions of this Lease. All rules shall be binding upon Tenant and enforceable by Landlord as if they were contained herein. Nothing contained in this Lease shall be construed as imposing upon Landlord any duty or obligation to enforce such rules, or the terms, conditions or covenants contained in any other lease, as against any other tenant, and Landlord shall not be liable to Tenant for the violation of such rules by any other tenant or its employees, agents, assignees, subtenants, invitees or licensees. Landlord shall use reasonable efforts not to enforce any rule or regulation in a manner which unreasonably discriminates among similarly situated tenants.

ARTICLE XVII

DAMAGE OR DESTRUCTION

17.1 If the Premises or the Building are totally or partially damaged or destroyed thereby rendering the Premises totally or partially inaccessible or unusable, then Landlord shall diligently repair and restore the Premises and the Building to substantially the same condition they were in prior to such damage or destruction; provided, however, that if in Landlord's reasonable judgment such repair and restoration cannot be completed within two hundred seventy (270) days after the occurrence of such damage or destruction (taking into account the time needed for effecting a satisfactory settlement with any insurance company involved, removal of debris, preparation of plans and issuance of all required governmental permits), then Landlord shall have the right to terminate this Lease by giving written notice of termination within forty five (45) days after the occurrence of such damage or destruction. If this Lease is terminated pursuant to this Article, then rent shall be apportioned (based on the portion of the Premises which is usable or used after such damage or destruction) and paid to the later of the date of termination or the date Tenant completely vacates and abandons the Premises on account of such damage and (if applicable) Landlord shall be entitled to any insurance proceeds received by Tenant that are attributable to improvements insured or required to be insured by Tenant that would remain in the Premises at the end of the Lease Term. If this Lease is not terminated as a result of such damage or destruction, then until such repair and restoration of the Premises are substantially complete, Tenant shall be required to pay rent only for the portion of the Premises that is usable while such repair and restoration are being made; provided, however, that (x) if such damage or destruction was caused by the act or omission of Tenant or any Agent of Tenant, then Tenant shall not be entitled to any such rent reduction and (y) if Tenant fails to immediately pay over to Landlord insurance proceeds when received from Tenant's insurance any such rent abatement shall end on the date when Landlord would have been able to substantially complete repair and restoration of the Premises had Tenant timely paid Landlord such insurance proceeds.

After receipt of all insurance proceeds (including proceeds of insurance maintained by Tenant), Landlord shall proceed with and bear the expenses of such repair and restoration of the Premises and the Building; provided, however, that (a) if such damage or destruction was caused by the act or omission of Tenant or any Agent of Tenant, then Tenant shall pay Landlord's deductible and the amount by which such expenses exceed the insurance proceeds, if any, actually received by Landlord on account of such damage or destruction (or, if Landlord fails to maintain the insurance required by Section 13.3, that Landlord would have received had Landlord maintained such insurance required by Section 13.3), (b) Tenant shall pay the amount by which the cost of restoring any item which Landlord is required to restore and Tenant is required to insure exceeds the insurance proceeds received with respect thereto, and (c) Landlord shall not be required to repair or restore any tenant improvements installed in the Premises (except to the extent Landlord receives proceeds therefor from Tenant's insurance), any Alterations or any other contents of the Premises (including Tenant's trade fixtures, decorations, furnishings, equipment or personal property). Notwithstanding anything herein to the contrary, Landlord shall have the right to terminate this Lease if (1) insurance proceeds plus deductibles are insufficient to pay the full cost of such repair and restoration (so long as Landlord maintains the insurance required by Section 13.3), (2) the holder of any Mortgage fails or refuses to make such insurance proceeds available for such repair and restoration, (3) zoning or other applicable Laws or regulations do not permit such repair and restoration, or (4) the damage to the Building exceeds thirty five percent (35%) of the replacement value of the Building.

17.2 If, within forty five (45) days after the occurrence of the damage or destruction described in Section 17.1, Landlord determines in its sole but reasonable judgment that the repairs and restoration cannot be substantially completed within two hundred seventy (270) days after the date of such damage or destruction as aforesaid, and provided Landlord does not elect to terminate this Lease pursuant to this Article, then Landlord shall promptly notify Tenant of such determination. For a period continuing through the later of the thirtieth (30th) day after the occurrence of the damage or destruction or the tenth (10th) day after receipt of such notice, Tenant shall have the right to terminate this Lease by providing written notice to Landlord (which date of such termination shall be not more than thirty (30) days after the date of Tenant's notice to Landlord). Notwithstanding any of the foregoing to the contrary, Tenant shall not have the right to terminate this Lease if the willful misconduct of Tenant or any Agent of Tenant shall have caused the damage or destruction.

ARTICLE XVIII **CONDEMNATION**

18.1 If one third or more of the Premises, or the use or occupancy thereof, shall be taken or condemned by any governmental or quasi-governmental authority for any public or quasi-public use or purpose or sold under threat of such a taking or condemnation (collectively, "**condemned**"), then this Lease shall terminate on the day prior to the date title thereto vests in such authority and rent shall be apportioned as of such date. If less than one third of the Premises or occupancy thereof is condemned, then this Lease shall continue in full force and effect as to the part of the Premises not so condemned, except that as of the date title vests in such authority Tenant shall not be required to pay rent with respect to the part of the Premises so condemned. Landlord shall notify Tenant of any condemnation contemplated by this Section

promptly after Landlord receives notice thereof. Within ten (10) days after receipt of such notice, Tenant shall have the right to terminate this Lease with respect to the remainder of the Premises not so condemned as of the date title vests in such authority if such condemnation renders said remainder of the Premises totally unusable for their intended purpose. Notwithstanding anything herein to the contrary, if twenty five percent (25%) or more of the Land or the Building is condemned, then whether or not any portion of the Premises is condemned, Landlord shall have the right to terminate this Lease as of the date title vests in such authority.

18.2 All awards, damages and other compensation paid on account of such condemnation shall belong to Landlord, and Tenant assigns to Landlord all rights to such awards, damages and compensation. Tenant shall not make any claim against Landlord or such authority for any portion of such award, damages or compensation attributable to damage to the Premises, value of the unexpired portion of the Lease Term, loss of profits or goodwill, leasehold improvements or severance damages. Nothing contained herein, however, shall prevent Tenant from pursuing a separate claim against the authority for relocation expenses and for the value of furnishings, equipment and trade fixtures installed in the Premises at Tenant's expense and which Tenant is entitled pursuant to this Lease to remove at the expiration or earlier termination of the Lease Term, provided that such claim shall in no way diminish the award, damages or compensation payable to or recoverable by Landlord in connection with such condemnation.

ARTICLE XIX **DEFAULT**

19.1 If there shall be an Event of Default, then the provisions of Section 19.2 shall apply. The periods herein specified (if any) within which Tenant is permitted to cure any default shall be in lieu of any cure period provided by applicable laws, all of which Tenant hereby waives.

19.2 Upon the occurrence of an Event of Default, Landlord shall have the right to pursue any one or more of the following remedies:

(a) Terminate this Lease, in which case Tenant shall immediately surrender the Premises to Landlord. In addition, with or without terminating this Lease, Landlord may re-enter, terminate Tenant's right of possession and take possession of the Premises. The provisions of this Article shall operate as a notice to quit, and Tenant hereby waives any other notice to quit or notice of Landlord's intention to re-enter the Premises or terminate this Lease. Landlord may proceed to recover possession of the Premises under applicable Laws, or by such other proceedings, including re-entry and possession, as may be applicable. If Landlord elects to terminate this Lease and/or elects to terminate Tenant's right of possession, everything contained in this Lease on the part of Landlord to be done and performed shall cease without prejudice, however, to Tenant's liability for all Base Rent, additional rent and other sums specified herein. Whether or not this Lease and/or Tenant's right of possession is terminated, Landlord shall have the right, at its sole option, to terminate any renewal or expansion right contained in this Lease and to grant or withhold any consent or approval pursuant to this Lease in its sole and absolute discretion. If Tenant fails to surrender the Premises, Landlord, in compliance with Law, may enter upon and take possession of the Premises and remove Tenant, Tenant's Personal Property

and any party occupying the Premises. Tenant shall pay Landlord, on demand, all past due Rent and other losses and damages Landlord suffers as a result of Tenant's Event of Default, including, without limitation, all Costs of Reletting (as hereinafter defined) and any deficiency that may arise from reletting or the failure to relet the Premises. "Costs of Reletting" shall include all reasonable costs and expenses incurred by Landlord in reletting or attempting to relet the Premises, including, without limitation, legal fees, brokerage commissions, the cost of alterations and the value of other concessions or allowances granted to a new tenant.

(b) Landlord shall use reasonable efforts to relet the Premises on such terms as Landlord in its sole discretion may determine (including a term different from the Term, rental concessions, and alterations to, and improvement of, the Premises); however, Landlord shall not be obligated to relet the Premises before leasing other portions of the Building. Landlord shall not be liable for, nor shall Tenant's obligations hereunder be diminished because of, Landlord's failure to relet the Premises or to collect rent due for such reletting.

19.3 In lieu of calculating damages under Section 19.2, Landlord may elect to receive as damages (x) the sum of (a) all Rent accrued through the date of termination of this Lease, and (b) an amount equal to the total Rent that Tenant would have been required to pay for the remainder of the Term discounted to present value, minus (y) the then present fair rental value of the Premises for the remainder of the Term, similarly discounted, after deducting all anticipated Costs of Reletting.

19.4 All rights and remedies of Landlord set forth in this Lease are cumulative and in addition to all other rights and remedies available to Landlord at law or in equity, including those available as a result of any anticipatory breach of this Lease. The exercise by Landlord of any such right or remedy shall not prevent the concurrent or subsequent exercise of any other right or remedy. No delay or failure by Landlord or Tenant to exercise or enforce any of its respective rights or remedies or the other party's obligations (except to the extent a time period is specified in this Lease therefor) shall constitute a waiver of any such or subsequent rights, remedies or obligations. Neither party shall be deemed to have waived any default by the other party unless such waiver expressly is set forth in a written instrument signed by the party against whom such waiver is asserted. If Landlord waives in writing any default by Tenant, such waiver shall not be construed as a waiver of any covenant, condition or agreement set forth in this Lease except as to the specific circumstances described in such written waiver.

19.5 If Landlord shall institute proceedings against Tenant and a compromise or settlement thereof shall be made, then the same shall not constitute a waiver of the same or of any other covenant, condition or agreement set forth herein, nor of any of Landlord's rights hereunder. Neither the payment by Tenant of a lesser amount than the monthly installment of Base Rent, additional rent or of any sums due hereunder nor any endorsement or statement on any check or letter accompanying a check for payment of rent or other sums payable hereunder shall be deemed an accord and satisfaction. Landlord may accept the same without prejudice to Landlord's right to recover the balance of such rent or other sums or to pursue any other remedy. Notwithstanding any request or designation by Tenant, Landlord may apply any payment received from Tenant to any payment then due. Only an express written acceptance of a surrender of this Lease executed by an authorized representative of Landlord and delivered to Tenant shall constitute an acceptance of surrender. Without limiting the foregoing, no re-entry or taking of possession of the Premises by Landlord, and no acceptance by Landlord of keys from Tenant, shall be considered an acceptance of a surrender of this Lease.

19.6 If Tenant fails to make any payment to any third party or to do any act herein required to be made or done by Tenant, then Landlord may, after written notice to Tenant, but shall not be required to, make such payment or do such act. The taking of such action by Landlord shall not be considered a cure of such default by Tenant or prevent Landlord from pursuing any remedy it is otherwise entitled to in connection with such default. If Landlord elects to make such payment or do such act, then all expenses incurred by Landlord, plus interest thereon at the Default Rate from the date incurred by Landlord to the date of payment thereof by Tenant, shall constitute additional rent due hereunder.

19.7 If Tenant fails to make any payment of Base Rent, additional rent or any other sum on or before the date such payment is due and payable (without regard to any grace period), then Landlord shall have the right to impose upon Tenant in writing a late charge of five percent (5%) of the amount of such payment. In addition, such payment and such late fee shall bear interest at the Default Rate from the date such payment or late fee, respectively, became due to the date of payment thereof by Tenant. Such late charge and interest shall constitute additional rent due hereunder without any notice or demand and shall be in addition to any and all other rights and remedies of Landlord.

19.8 As security for the performance of Tenant's obligations, Tenant grants to Landlord a lien upon and a security interest in Tenant's existing or hereafter acquired personal property, inventory, furniture, furnishings, fixtures, equipment, licenses, permits and all other tangible and intangible property, assets and accounts, and all additions, modifications, products and proceeds thereof. Such lien shall be in addition to any and all rights of Landlord available under applicable law. Tenant acknowledges and agrees that Landlord may file such financing statements and other documents as Landlord may determine to be appropriate, and Tenant, within five (5) days after request from time to time, shall execute, acknowledge and deliver to Landlord any statement or document evidencing or establishing such lien and security interest which may be requested by Landlord. During the pendency of an Event of Default, Tenant appoints Landlord as Tenant's attorney-in-fact to execute any such document for Tenant. During any period that Tenant is in default under this Lease, Tenant shall not sell, transfer or remove from the Premises any of the aforementioned tangible property without Landlord's prior written consent, unless the same shall be promptly replaced with similar items of comparable value.

19.9 If more than one natural person or entity shall constitute Tenant, then the liability of each such person or entity shall be joint and several. If Tenant is a general partnership or other entity the partners or members of which are subject to personal liability, then the liability of each such partner or member shall be joint and several. No waiver, release or modification of the obligations of any such person or entity shall affect the obligations of any other such person or entity.

ARTICLE XX
BANKRUPTCY

20.1 Upon occurrence of an Event of Bankruptcy, Landlord shall have all rights and remedies available pursuant to Article XIX; provided, however, that while a Case is pending, Landlord's right to terminate this Lease shall be subject, to the extent required by the Bankruptcy Code, to any rights of the Trustee to assume or assume and assign this Lease pursuant to the Bankruptcy Code. After the commencement of a Case: (i) Trustee shall perform all post-petition obligations of Tenant under this Lease; and (ii) if Landlord is entitled to damages (including unpaid rent) pursuant to the terms of this Lease, then all such damages shall be entitled to administrative expense priority pursuant to the Bankruptcy Code. Tenant acknowledges that this Lease is a lease of nonresidential real property and therefore Tenant, as the debtor in possession, or the Trustee shall not seek or request any extension of time to assume or reject this Lease or to perform any obligations of this Lease which arise from or after the order of relief. Any person or entity to which this Lease is assigned pursuant to the Bankruptcy Code shall be deemed without further act or deed to have assumed all of the obligations arising under this Lease on and after the date of assignment, and any such assignee shall upon request execute and deliver to Landlord an instrument confirming such assumption. Trustee shall not have the right to assume or assume and assign this Lease unless Trustee promptly (a) cures all defaults under this Lease, (b) compensates Landlord for damages incurred as a result of such defaults, (c) provides adequate assurance of future performance on the part of Trustee as debtor in possession or Trustee's assignee, and (d) complies with all other requirements of the Bankruptcy Code. If Trustee desires to assume and assign this Lease to any person who shall have made a bona fide offer, then Trustee shall give Landlord written notice of such proposed assignment (which notice shall set forth the name and address of such person, all of the terms and conditions of such offer, and the adequate assurance to be provided Landlord to assure such person's future performance under this Lease) no later than fifteen (15) days after receipt by Trustee of such offer, but in no event later than thirty (30) days prior to the date Trustee shall make application to the appropriate court for authority and approval to enter into such assignment and assumption, and Landlord shall thereupon have the prior right and option, to be exercised by notice to Trustee given at any time prior to the effective date of such proposed assignment, to accept (or to cause Landlord's designee to accept) an assignment of this Lease upon the same terms and conditions and for the same consideration, if any, as the bona fide offer made by such person, less any brokerage commissions which may be payable out of the consideration to be paid by such person for the assignment of this Lease. If Trustee fails to assume or assume and assign this Lease in accordance with the requirements of the Bankruptcy Code within sixty (60) days after the initiation of the Case (or such other period as may be provided by the Bankruptcy Code or allowed by the United States Bankruptcy Court for same), then Trustee shall be deemed to have rejected this Lease. If this Lease is rejected or deemed rejected, then Landlord shall have all rights and remedies available to it pursuant to Article XIX. At any time during the Term, upon not less than five (5) days prior written notice, Tenant shall provide Landlord with the most current financial statement for Tenant and any such person and financial statements for the two (2) years prior to the current financial statement year. Such statements are to be certified by Tenant to be true, correct and complete, prepared in accordance with generally accepted accounting principles and, if it is the normal practice of Tenant, audited by any independent certified public accountant.

ARTICLE XXI
SUBORDINATION

21.1 This Lease is subject and subordinate to the lien, provisions, operation and effect of all Mortgages, to all funds and indebtedness intended to be secured thereby, and to all renewals, extensions, modifications, recastings or refinancings thereof. Said subordination and the provisions of this Section shall be self-operative and no further instrument of subordination shall be required to effectuate such subordination. The holder of any Mortgage to which this Lease is subordinate shall have the right (subject to any required approval of the holders of any superior Mortgage) at any time to declare this Lease to be superior to the lien, provisions, operation and effect of such Mortgage.

21.2 Tenant shall at Landlord's request promptly execute any requisite document confirming such subordination. During the pendency of an Event of Default, Tenant appoints Landlord as Tenant's attorney in fact to execute any such document for Tenant. Tenant waives the provisions of any statute or rule of law now or hereafter in effect which may give or purport to give Tenant any right to terminate or otherwise adversely affect this Lease and Tenant's obligations hereunder in the event any foreclosure proceeding is prosecuted or completed or in the event the Building, the Land or Landlord's interest therein is transferred by foreclosure, by deed in lieu of foreclosure or otherwise. At the request of such transferee and assumption of Landlord's obligations as required hereby, Tenant shall attorn to such transferee and shall recognize such transferee as the landlord under this Lease. Tenant agrees that upon any such attornment, such transferee shall not be (a) bound by or required to credit Tenant with any prepayment of the Base Rent or additional rent more than thirty (30) days in advance or any deposit, rental security or any other sums deposited with any prior landlord under the Lease (including Landlord) unless said sum is actually received by such transferee, (b) bound by any amendment, modification or termination of this Lease made without the consent of the holder of each Mortgage existing as of the date of such amendment, (c) liable for any breach, act or omission of any prior landlord under the Lease (including Landlord) or any damages arising therefrom; (d) subject to any offsets or defenses which Tenant might have against any prior landlord (including Landlord), (e) liable for any late completion of any construction of the Premises or tenant improvement work to the Premises commenced or agreed to by any prior landlord under the Lease (including Landlord), (f) liable for payment of any damages, fees or penalties payable by any landlord under the Lease (including Landlord) to Tenant including but not limited to fees or penalties for failure to deliver the Premises in a timely fashion, or (g) bound by any obligation which may appear in this Lease to pay any sum of money to Tenant; provided, however, that after succeeding to Landlord's interest under this Lease, such transferee shall agree to perform in accordance with the terms of this Lease all obligations of Landlord arising after the date of transfer. Within ten (10) days after the request of such transferee, Tenant shall execute, acknowledge and deliver any requisite or appropriate document submitted to Tenant confirming such attornment.

ARTICLE XXII
HOLDING OVER

22.1 Tenant acknowledges that it is extremely important that Landlord have substantial advance notice of the date on which Tenant will vacate the Premises, and that if Tenant fails to surrender the Premises or any portion thereof at the expiration or earlier termination of the Lease Term or upon Landlord's re-entry following an Event of Default, then it will be conclusively presumed that the value to Tenant of remaining in possession, and the loss that will be suffered by Landlord as a result thereof, far exceed the Base Rent and additional rent that would have been payable had the Lease Term continued during such holdover period. Therefore, if Tenant (or anyone claiming through or under Tenant) does not immediately surrender the Premises or any portion thereof upon the expiration or earlier termination of the Lease Term or upon Landlord's re-entry following an Event of Default, then the rent payable by Tenant hereunder shall be increased to equal (1) for each of the first (1st) and second (2nd) months of such holdover, the greater of (i) one hundred fifty percent (150%) of the fair market rent for the entire Premises, or (ii) the one hundred fifty percent (150%) of the then fully escalated Base Rent and additional rent, and (2) for each month of holdover thereafter, the greater of (x) two hundred percent (200%) of the fair market rent for the entire Premises, or (y) two hundred percent (200%) of the then fully escalated Base Rent and additional rent. Such rent shall be computed by Landlord and paid by Tenant on a monthly basis and shall be payable on the first day of such holdover period and the first day of each calendar month thereafter during such holdover period until the Premises have been vacated. Notwithstanding any other provision of this Lease, Landlord's acceptance of such rent shall not in any manner adversely affect Landlord's other rights and remedies, including Landlord's right to evict Tenant and to recover all damages, and Tenant shall save Landlord, its agents and employees, harmless and will exonerate, defend and indemnify Landlord, its agents and employees, from and against any and all damages which Landlord may suffer on account of Tenant's hold-over in the Premises after the expiration or prior termination of the Lease Term. Any such holdover shall be deemed to be a tenancy at sufferance and not a tenancy at will. In no event shall any holdover be deemed a permitted extension or renewal of the Lease Term, and nothing contained herein shall be construed to constitute Landlord's consent to any holdover or to give Tenant any right with respect thereto. The provisions of this Section 22.1 expressly survive termination of the Lease or of Tenant's right to possession.

ARTICLE XXIII
COVENANTS OF LANDLORD

23.1 Landlord covenants that it has the right to enter into this Lease, and that if Tenant shall perform timely all of its obligations hereunder, then, subject to the provisions of this Lease, Tenant shall during the Lease Term peaceably and quietly occupy and enjoy the full possession of the Premises (i.e., quiet enjoyment) without hindrance by Landlord, its employees or agents.

23.2 Subject to other applicable terms and provisions expressly provided in this Lease, Landlord reserves the following rights: (a) to change the street address and name of the Building provided that Tenant's access to the Premises is not permanently, materially and adversely affected; (b) to change the arrangement and location of entrances, passageways, doors, doorways, corridors, elevators, stairs, toilets or other public parts of, and make additions to, the Building provided that Tenant's access to the Premises is not permanently, materially and adversely affected; (c) to erect, use and maintain pipes, wires, structural supports, ducts and

conduits in and through the plenum areas of the Premises; (d) to grant to anyone the exclusive right to conduct any particular business in the Building not inconsistent with Tenant's permitted use of the Premises; (e) to exclusively use and/or lease the roof areas, the sidewalks and other exterior areas; (f) to re-subdivide the Land or to combine the Land with other lands; (g) to relocate any parking areas designated for Tenant's use; (h) intentionally deleted; (i) to construct improvements (including kiosks) on the Land and in the public and Common Areas of the Building; (j) to prohibit smoking in the entire Building or portions thereof (including the Premises), and to restrict smoking to certain designated areas of the Land, so long as such prohibitions are in accordance with applicable law; and (k) if any excavation or other substructure work shall be made or authorized to be made upon land adjacent to the Building or the Land, to enter the Premises for the purpose of doing such work as is required to preserve the walls of the Building and to preserve the land from injury or damage and to support such walls and land by proper foundations. Subject to the other applicable terms and provisions expressly provided in this Lease, Landlord may exercise any or all of the foregoing rights without being deemed to be guilty of an eviction, actual or constructive, or a disturbance of Tenant's business or use or occupancy of the Premises and Tenant shall have no claim against Landlord in connection therewith. With respect to (b), (c), (e), (g), (i) and (k) above, Landlord shall use reasonable efforts to minimize interference with Tenant's normal business operations in the Premises (subject, however, in all cases to governmental requirements, emergencies and/or temporary maintenance and repair activities, and in no event shall Landlord have any obligation to employ contractors or labor at overtime or other premium pay rates or incur any other overtime costs).

ARTICLE XXIV
PARKING

24.1 During the Lease Term, Tenant and its employees, visitors and other invitees shall be entitled to use unreserved parking spaces for standard sized passenger automobiles in the Parking Facilities in an amount equal to the Parking Space Allotment, subject to Landlord's rights pursuant to the remainder of this Section and such rules and regulations as Landlord may establish from time to time. Such parking shall be in non-exclusive, unassigned spaces on a self-park, attendant-park, valet or other basis, as from time to time prescribed by Landlord, and the charge for such permits shall be the prevailing rate charged from time to time by Landlord or the Operator (currently \$510.00 per space per month, subject to change at any time and from time to time without notice), plus all taxes or other governmental surcharges. Such charges shall be paid monthly in advance to the Operator. Except as otherwise provided herein, contracts for parking permits shall be with the Operator and shall contain the same terms as are usually contained in contracts with other customers of the Operator. Tenant shall not use the Parking Facilities for the servicing or extended storage of vehicles. Tenant shall not assign, sublet or transfer any permits hereunder, except in connection with any assignment or sublease permitted pursuant to Article VII hereof where parking is provided for in the sublease or assignment. Landlord reserves the right to institute either a Parking Facilities operator system, which may include self-park, attendant-park, valet or other parking arrangements, or to otherwise change the parking system. Notwithstanding anything to the contrary herein, Landlord does not guarantee the availability of any such monthly parking permits to Tenant during the second (2nd) or any subsequent month of the Lease Term if and to the extent that Tenant does not purchase any such

monthly parking permits during the first (1st) month and each subsequent month of the Lease Term (it being understood that if Tenant does not timely purchase any such monthly parking contracts as provided herein but later notifies Landlord in writing of its desire to purchase same, then Landlord shall, upon not less than sixty (60) days' prior written notice from Tenant, provide Tenant the right to purchase its desired number of monthly parking permits (up to the Parking Space Allotment in the aggregate). Tenant and its employees shall observe reasonable safety precautions in the use of the Parking Facilities or any other parking area and shall at all times abide by all rules and regulations governing the use of the Parking Facilities. Tenant acknowledges that particular parking facilities, areas or spaces may be designated for exclusive use by particular tenants, occupants, visitors or other users, either generally or at particular times, and Tenant shall comply with all such designations and cause its employees, visitors and other invitees to do the same. Landlord reserves the right to close the Parking Facilities or any other parking area during periods of unusually inclement weather or for alterations, improvements or repairs. Landlord does not assume any responsibility, and shall not be held liable, for any damage or loss to any automobile or personal property in or about the Parking Facilities, or for any injury sustained by any person in or about the Parking Facilities. Landlord shall not be liable to Tenant and this Lease shall not be affected if any parking rights hereunder are impaired by any Law imposed after the Lease Commencement Date. Landlord reserves the right to determine whether the Parking Facilities are becoming crowded and to allocate and assign parking spaces among Tenant and the other tenants provided that the Parking Space Allotment will not be reduced thereby. Said Parking Space Allotment shall be paid for by Tenant at the then current prevailing rate in the Parking Facilities, as such rate may vary from time to time.

ARTICLE XXV
GENERAL PROVISIONS

25.1 Tenant acknowledges that neither Landlord nor any broker, agent or employee of Landlord has made any representation or promise with respect to the Premises or any portion of the Building except as herein expressly set forth, and no right, privilege, easement or license is being acquired by Tenant except as herein expressly set forth.

25.2 Nothing contained in this Lease shall be construed as creating any relationship between Landlord and Tenant other than that of landlord and tenant, and no estate shall pass out of Landlord. Landlord and Tenant intend that their relationship hereunder shall be that of landlord and tenant pursuant to applicable Law. Tenant's interest hereunder is not subject to levy and sale and is not assignable or transferable (for security purposes, collateral purposes or otherwise), except as expressly provided in Article VII of this Lease. Tenant shall not use the name of the Building for any purpose other than as the address of the business to be conducted by Tenant in the Premises, use the name of the Building as Tenant's business address after Tenant vacates the Premises, or do or permit to be done anything in connection with Tenant's business or advertising which in the reasonable judgment of Landlord may reflect unfavorably on Landlord or the Building or confuse or mislead the public as to any apparent connection or relationship between Landlord, the Building and Tenant.

25.3 Landlord and Tenant each warrants to the other that in connection with this Lease it has not employed or dealt with any broker, agent or finder, other than the Brokers. It is understood that Landlord shall pay Landlord's Broker and Tenant's Broker pursuant to separate agreements between Landlord and the Brokers. Tenant shall indemnify and hold Landlord harmless from and against any claim for brokerage or other commissions asserted by any broker, agent or finder employed by Tenant or with whom Tenant has dealt, other than the Brokers. Landlord shall indemnify and hold Tenant harmless from and against any claim for brokerage or other commissions asserted by Landlord's Broker and Tenant's Broker and any other broker, agent or finder employed by Landlord or with whom Landlord has dealt. Tenant's and Landlord's indemnities set forth in this Section shall survive the expiration or earlier termination of the Lease Term.

25.4 At any time and from time to time, upon not less than ten (10) days' prior written notice, Tenant and each subtenant, assignee, licensee or concessionaire or occupant of Tenant shall execute, acknowledge and deliver to Landlord and/or any other person or entity designated by Landlord, a written statement certifying: (a) that this Lease is unmodified and in full force and effect (or if there have been modifications, that this Lease is in full force and effect as modified and stating the modifications); (b) the dates to which the rent and any other charges have been paid; (c) to Tenant's knowledge, whether or not Landlord is in default in the performance of any obligation, and if so, specifying the nature of such default; (d) whether or not Tenant is in default of the performance of any obligation, and if so, specifying the nature of such default; (e) that this Lease is subject and subordinate to all Mortgages encumbering the Building or the Land; (f) that Tenant has accepted the Premises and that all work thereto has been completed (or if such work has not been completed, specifying the incomplete work); and (g) such other matters as Landlord may reasonably request. Any such statement may be relied upon by any owner of the Building or the Land, any prospective purchaser of the Building or the Land, any holder or prospective holder of a Mortgage or any other person or entity. Tenant acknowledges that time is of the essence to the delivery of such statements and that Tenant's failure to deliver timely such statements may cause substantial damages resulting from, for example, delays in obtaining financing. Accordingly, if Tenant fails to so execute and deliver such statement within such ten (10) day period, then Landlord shall be entitled to send Tenant a second notice requesting such execution and delivery of such statement ("**Second Notice**"), and if Tenant fails to execute and deliver such statement within three (3) days after the Second Notice, then Tenant shall pay to Landlord a fee in the amount of Five Hundred and 00/100 Dollars (\$500.00) per day for each day beyond the third (3rd) day after the Second Notice that Tenant fails to execute and deliver such statement. Such fee shall be in addition to Landlord's other remedies hereunder.

25.5 TO THE EXTENT PERMITTED BY LAW, LANDLORD, TENANT, ALL GUARANTORS AND ALL GENERAL PARTNERS EACH WAIVES TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM BROUGHT IN CONNECTION WITH ANY MATTER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT HEREUNDER, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM OF INJURY OR DAMAGE. TENANT CONSENTS TO SERVICE OF PROCESS AND ANY PLEADING RELATING TO ANY SUCH ACTION AT THE PREMISES; PROVIDED, HOWEVER, THAT NOTHING HEREIN SHALL BE CONSTRUED AS REQUIRING SUCH SERVICE AT THE PREMISES. TENANT WAIVES ANY RIGHT TO RAISE ANY NON-

COMPULSORY COUNTERCLAIM IN ANY SUMMARY OR EXPEDITED ACTION OR PROCEEDING INSTITUTED BY LANDLORD. LANDLORD, TENANT, ALL GUARANTORS AND ALL GENERAL PARTNERS EACH WAIVES ANY OBJECTION TO THE VENUE OF ANY ACTION FILED IN ANY COURT SITUATED IN THE JURISDICTION IN WHICH THE BUILDING IS LOCATED, AND WAIVES ANY RIGHT, CLAIM OR POWER, UNDER THE DOCTRINE OF FORUM NON CONVENIENS OR OTHERWISE, TO TRANSFER ANY SUCH ACTION TO ANY OTHER COURT.

25.6 All notices or other communications required under this Lease shall be in writing and shall be deemed duly given and received when delivered in person (with receipt therefor), on the next business day after deposit with a recognized overnight delivery service, or on the second day after being sent by certified or registered mail, return receipt requested, postage prepaid, to the following addresses: (a) if to Landlord, at the Landlord Notice Address specified in Article I; (b) if to Tenant, at the Tenant Notice Address specified in Article I. Either party may change its address for the giving of notices by written notice given in accordance with this Section. If Landlord or the holder of any Mortgage notifies Tenant in writing that a copy of any notice to Landlord shall be sent to such holder at a specified address, then Tenant shall send (in the manner specified in this Section and at the same time such notice is sent to Landlord) a copy of each such notice to such holder, and no such notice shall be considered duly sent unless such copy is so sent to such holder. Any such holder shall have thirty (30) days after receipt of such notice to cure any Landlord default before Tenant may exercise any remedy (provided that in the case of a Landlord default arising from an act or omission which cannot be reasonably remedied within said thirty (30) day period, then the holder of any Mortgage shall have as long as reasonably necessary to remedy such act or omission provided that (i) such holder commences such remedy and notifies Tenant within said thirty (30) day period of holder's desire to remedy, and (ii) holder pursues completion of such remedy with due diligence following such giving of notice and following the time when holder should have become entitled under the Mortgage to remedy the same). Any cure of Landlord's default by such holder shall be treated as performance by Landlord.

25.7 Each provision of this Lease shall be valid and enforceable to the fullest extent permitted by law. If any provision of this Lease or the application thereof to any person or circumstance shall to any extent be invalid or unenforceable, then such provision shall be deemed to be replaced by the valid and enforceable provision most substantively similar to such invalid or unenforceable provision, and the remainder of this Lease and the application of such provision to persons or circumstances other than those as to which it is invalid or unenforceable shall not be affected thereby. Nothing contained in this Lease shall be construed as permitting Landlord to charge or receive interest in excess of the maximum rate allowed by law.

25.8 Feminine, masculine or neuter pronouns shall be substituted for those of another form, and the plural or singular shall be substituted for the other number, in any place in which the context may require such substitution.

25.9 The provisions of this Lease shall be binding upon and inure to the benefit of the parties and each of their respective representatives, successors and assigns, subject to the provisions herein restricting assignment or subletting.

25.10 This Lease contains and embodies the entire agreement of the parties hereto and supersedes all prior agreements, negotiations, letters of intent, proposals, representations, warranties, understandings, suggestions and discussions, whether written or oral, between the parties hereto. Any representation, inducement, warranty, understanding or agreement that is not expressly set forth in this Lease shall be of no force or effect. This Lease may be modified or changed in any manner only by an instrument signed by both parties. This Lease includes and incorporates all exhibits, schedules and riders referenced herein, all of which are attached hereto. Tenant shall, at Landlord's request, promptly execute any requisite document, certificate or instrument that is reasonably necessary or desirable to clarify or carry out the force and effect of any terms or conditions of, or obligation of Tenant under, this Lease.

25.11 This Lease shall be governed by the Laws of the jurisdiction in which the Building is located, without regard to the application of choice of law principles. There shall be no presumption that this Lease be construed more strictly against the party who itself or through its agent prepared it (it being agreed that all parties hereto have participated in the preparation of this Lease and that each party had the opportunity to consult legal counsel before the execution of this Lease). No custom or practice which may evolve between the parties in the administration of the terms of this Lease shall be construed to waive Landlord's right to insist on Tenant's strict performance of the terms of this Lease.

25.12 Headings are used for convenience and shall not be considered when construing this Lease.

25.13 The submission of an unsigned copy of this document to Tenant shall not constitute an offer or option to lease the Premises. This Lease shall become effective and binding only upon execution and delivery by both Landlord and Tenant.

25.14 Time is of the essence with respect to Tenant's obligations hereunder.

25.15 This Lease (and all exhibits hereto) may be executed in multiple counterparts, each of which shall be deemed an original and all of which together constitute one and the same document. Electronic copies of signatures delivered by any method shall have the same binding effect as original signatures, and an electronic copy of the Lease containing the signatures (original, faxed or emailed) of the parties is binding. This Lease (and all exhibits hereto) may be signed by Landlord or Tenant (as applicable) with an electronic signature or signature stamp, which electronic signature or signature stamp shall have the same binding effect as if it were an original signature.

25.16 Neither this Lease nor a memorandum thereof shall be recorded.

25.17 Except as otherwise provided in this Lease, any additional rent or other sum owed by Tenant to Landlord, and any cost, expense, damage or liability incurred by Landlord for which Tenant is liable, shall be considered additional rent payable pursuant to this Lease to be paid by Tenant no later than thirty (30) days after the date Landlord notifies Tenant of the amount thereof. If Tenant has not objected to any statement of additional rent which is rendered by Landlord to Tenant within one hundred eighty (180) days after Landlord has rendered the same to Tenant, then the same shall be deemed to be a final account between Landlord and Tenant not subject to any further dispute.

25.18 Tenant's liabilities and obligations with respect to the period prior to the expiration or earlier termination of the Lease Term shall survive such expiration or earlier termination. Landlord's liabilities and obligations with respect to refund of the security deposit or overpayments by Tenant of Real Estate Taxes or Operating Charges, if and to the extent required by the provisions of this Lease, shall survive the expiration or earlier termination of this Lease.

25.19 If Landlord or Tenant is in any way delayed or prevented from performing any obligation (except, with respect to Tenant, its obligations to pay rent and other sums due under this Lease, any obligation set forth in **Exhibit B**, any obligation with respect to insurance pursuant to Article XIII, any obligation to give notice with respect to extensions, expansions or otherwise, and its obligation to vacate the Premises at the expiration or earlier termination of the Lease Term) due to fire, act of God, pandemics, epidemics, and outbreaks of communicable diseases, or any cause beyond Landlord's or Tenant's (as applicable) reasonable control (whether similar or dissimilar to the foregoing events), governmental act or failure to act, strike, labor dispute, inability to procure materials, or any cause beyond Landlord's or Tenant's (as applicable) reasonable control (whether similar or dissimilar to the foregoing events), then the time for performance of such obligation shall be excused for the period of such delay or prevention and extended for a period equal to the period of such delay or prevention. No such force majeure event shall delay the Lease Commencement Date or excuse the timely payment of all items of rent by Tenant. Financial disability or hardship shall never constitute a force majeure event.

25.20 Landlord's review, approval and consent powers (including the right to review plans and specifications) are for its benefit only. Such review, approval or consent (or conditions imposed in connection therewith) shall be deemed not to constitute a representation concerning legality, safety or any other matter.

25.21 The deletion of any printed, typed or other portion of this Lease shall not evidence the parties' intention to contradict such deleted portion. Such deleted portion shall be deemed not to have been inserted in this Lease.

25.22 At the expiration or earlier termination of the Lease Term, Tenant shall deliver to Landlord all keys and security cards to the Building and the Premises, whether such keys were furnished by Landlord or otherwise procured by Tenant, and shall inform Landlord of the combination of each lock, safe and vault, if any, in the Premises.

25.23 Tenant and the person executing and delivering this Lease on Tenant's behalf each represents and warrants that such person is duly authorized to so act; that Tenant is duly organized, is qualified to do business in the jurisdiction in which the Building is located, is in good standing under the Laws of the state of its organization and the Laws of the jurisdiction in which the Building is located, and has the power and authority to enter into this Lease, and that all action required to authorize Tenant and such person to enter into this Lease has been duly taken.

25.24 Any elimination or shutting off of light, air, or view by any structure which may be erected on lands adjacent to the Building, or any noise in connection with activities permitted by this Lease, shall in no way effect this Lease or impose any liability on Landlord.

25.25 In the event Landlord or Tenant is required or elects to take legal action against the other party to enforce the provisions of this Lease, then the prevailing party in such action shall be entitled to collect from the other party its costs and expenses incurred in connection with the legal action (including reasonable attorneys' fees and court costs). Notwithstanding the foregoing, if Landlord shall take any legal action for collection of rent or file any eviction proceedings (whether summary or otherwise) for the nonpayment of rent, and Tenant shall make payment of such rent prior to the rendering of any judgment, the Landlord shall be entitled to collect and Tenant shall pay as additional rent all filing fees and other costs in connection therewith (including reasonable attorneys' fees).

25.26 Landlord and Tenant shall keep the Lease (including the existence, terms and conditions thereof) strictly confidential and shall not disclose same to any person or entity other than a Permitted Person, and then only on a need to know basis. A "**Permitted Person**" shall be defined as the officers and directors of Landlord or Tenant, the employees of Landlord or Tenant who are involved in lease administration, Tenant's or Landlord's certified public accountants, lenders, attorneys or agents who have responsibilities related to the Lease, or any person or entity to whom disclosure is required by applicable judicial or governmental authority, and with respect to Landlord, to its investors and its prospective lenders and investors and to any prospective purchasers of the Building or of any interests therein. Prior to disclosing same to any Permitted Person, Tenant and Landlord shall instruct such Permitted Person to abide by this confidentiality provision.

25.27 As an inducement to Landlord to enter into this Lease, Tenant hereby represents and warrants that: (i) Tenant is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on any list issued by the Office of Foreign Assets Control of the United States Department of the Treasury ("**OFAC**") pursuant to Executive Order 13224 or any similar list or any law, order, rule or regulation or any Executive Order of the President of the United States as a terrorist, "Specially Designated National and Blocked Person" or other banned or blocked person (any such person, group, entity or nation being hereinafter referred to as a "**Prohibited Person**"); (ii) Tenant is not (nor is it owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) from and after the effective date of the above-referenced Executive Order, Tenant (and any person, group, or entity which Tenant controls, directly or indirectly) has not knowingly conducted nor will knowingly conduct business nor has knowingly engaged nor will knowingly engage in any transaction or dealing with any Prohibited Person in violation of the U.S. Patriot Act or any OFAC rule or regulation, including, without limitation, any assignment of this Lease or any subletting of all or any portion of the Premises or the making or receiving of any contribution of funds, goods or services to or for the benefit of a Prohibited Person in violation of the U.S. Patriot Act or any OFAC rule or regulation. In connection with the foregoing, it is expressly understood and agreed that (x) any breach by Tenant of the foregoing representation s and warranties shall be deemed a default by Tenant under Article XIX of this Lease and shall be covered by the indemnity provisions of this Lease,

(y) Tenant shall be responsible for ensuring that all assignees of this Lease and all subtenants or other occupants of the Premises comply with the foregoing representations and warranties, and (z) the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease.

[Signature pages follow]

LANDLORD:

COLUMBIA REIT – 116 HUNTINGTON, LLC, a
Delaware limited liability company

By: Columbia Property Trust Operating Partnership, L.P., a
Delaware limited partnership, its sole member

By: Columbia Property Trust Inc., a Maryland
corporation, its general partner

By: /s/ Ted Koltis

Name: Ted Koltis

Title: EVP

TENANT:

BICARA THERAPEUTICS INC., a Delaware corporation

By: /s/ Ryan Cohlhepp

Name: Ryan Cohlhepp

Title: President & COO, Bicara Therapeutics Inc.

SUBSIDIARIES

| Legal Name | Jurisdiction of Incorporation |
|-------------------------------|--------------------------------------|
| Bicara Securities Corporation | Massachusetts |