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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-42271

BICARA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-2903745**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
116 Huntington Ave Suite 703 Boston, Massachusetts	**02116**
(Address of Principal Executive Offices)	(Zip Code)

617-468-4219
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	BCAX	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

As of November 8, 2024, the registrant had 54,415,619 shares of common stock, $0.0001 par value per share outstanding.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

We are subject to numerous risks and uncertainties, including those further described below in the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following considerations, among others, may offset our competitive strengths or have a negative effect on our business strategy, which could materially adversely affect our business, financial conditions, results of operations, future growth prospects, or cause a decline in the price of our common stock:

- 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 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 ficerafusp alfa. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize ficerafusp alfa, or if we experience delays in doing so, our business will be materially harmed.

- The regulatory approval processes of the U.S. Food and Drug Administration 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 ficerafusp alfa and any future product candidates.

- Ficerafusp alfa 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 ficerafusp alfa 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.

- We currently and in the future may depend on other third-party collaborators for the discovery, development and commercialization of ficerafusp alfa 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 not yet demonstrated an ability to generate revenue, obtain regulatory approval, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Form 10-Q include, but are not limited to, statements about:

- the initiation timing, progress, results and cost of ficerafusp alfa, including the Phase 2/3 trial in head and neck squamous cell carcinoma, or HNSCC, and the potential expansion Phase 1 trial in additional HNSCC 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 ficerafusp alfa 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 ficerafusp alfa, and other positive results;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of ficerafusp alfa;
- the timing, scope and likelihood of regulatory filings and approvals, for ficerafusp alfa and future product candidates, including the timing of INDs and final FDA approval of ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of ficerafusp alfa;
- our ability to obtain and maintain regulatory approval of ficerafusp alfa;
- our ability to commercialize ficerafusp alfa, if approved;
- the pricing and reimbursement of ficerafusp alfa, if approved;
- the implementation of our business model, and strategic plans for our business, ficerafusp alfa and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering ficerafusp alfa 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;

- future agreements with third parties in connection with the development and commercialization of ficerafusp alfa and any other approved product;
- the size and growth potential of the markets for ficerafusp alfa and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of ficerafusp alfa;
- regulatory developments in the U.S., 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 ficerafusp alfa 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;
- 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 Form 10-Q. 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 Form 10-Q and the documents that we reference in this Form 10-Q and have filed with the SEC as exhibits, of which this Form 10-Q 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 Form 10-Q represent our views as of the date of this Form 10-Q. 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 Form 10-Q.

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 Form 10-Q, 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.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except shares and per share data)

	September 30, 2024	December 31, 2023
Assets	*(Unaudited)*	
Current assets:		
Cash and cash equivalents	$ 520,758	$ 230,440
Prepaid expenses and other assets	756	633
Total current assets	521,514	231,073
Property and equipment, net	130	202
Right of use asset – operating lease	414	613
Other assets	2,115	2,094
Total assets	$ 524,173	$ 233,982
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,531	$ 2,142
Accounts payable – related party	431	1,044
Accrued expenses and other current liabilities	10,410	8,053
Accrued expenses and other current liabilities – related party	1,801	3,561
Operating lease liability – current portion	308	285
Total current liabilities	14,481	15,085
Operating lease liability – net of current portion	137	372
Other liabilities	—	17
Total liabilities	14,618	15,474
Commitments and Contingencies:		
Seed Series redeemable convertible preferred stock, $0.0001 par value, 0 and 81,790,144 authorized; issued and outstanding as of September 30, 2024 and December 31, 2023, respectively (liquidation preference of $0 and $81,790 as of September 30, 2024, and December 31, 2023, respectively)	—	81,525
Series B redeemable convertible preferred stock, $0.0001 par value, 0 and 105,595,101 shares authorized; issued and outstanding as of September 30, 2024 and December 31, 2023, respectively (liquidation preference of $0 and $108,235 as of September 30, 2024 and December 31, 2023, respectively);	—	121,148
Series C redeemable convertible preferred stock, $0.0001 par value, 0 and 119,599,872 shares authorized; issued and outstanding as of September 30, 2024 and December 31, 2023, respectively (liquidation preference of $0 and $165,000 as of September 30, 2024 and December 31, 2023, respectively)	—	164,604
Total redeemable convertible preferred stock	—	367,277
Stockholders' equity (deficit):		
Preferred stock $0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 500,000,000 and 365,000,000 shares authorized; 54,424,994 and 711,895 shares issued and 54,409,708 and 640,386 shares outstanding as of September 30, 2024 and December 31, 2023, respectively	7	2
Additional paid-in capital	709,607	4,250
Accumulated deficit	(200,059)	(153,021)
Total stockholders' equity (deficit)	509,555	(148,769)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 524,173	$ 233,982

See accompanying notes to condensed consolidated financial statements

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands except shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development - related party	$ 2,310	$ 2,271	$ 7,400	$ 6,511
Research and development	13,554	4,668	36,336	13,544
General and administrative	4,764	2,591	12,016	6,147
Total operating expenses	20,628	9,530	55,752	26,202
Loss from operations	(20,628)	(9,530)	(55,752)	(26,202)
Other (expenses) income				
Interest income	3,147	13	8,715	13
Change in fair value of Series B preferred stock tranche rights liability	—	(13,328)	—	(13,356)
Total other income (expense)	3,147	(13,315)	8,715	(13,343)
Net loss before income taxes	(17,481)	(22,845)	(47,037)	(39,545)
Income tax expense	–	–	(1)	–
Net loss	$ (17,481)	$ (22,845)	$ (47,038)	$ (39,545)
Net Loss per share, basic and diluted	$ (1.60)	$ (38.23)	$ (11.27)	$ (70.18)
Weighted-average number common shares outstanding, basic and diluted	10,901,138	597,586	4,174,353	563,483

See accompanying notes to condensed consolidated financial statements

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited, in thousands except shares)

	Seed Series Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Equity		Additional Paid in Capital	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
December 31, 2022	81,790,144	$ 81,525	—	$ —	504,544	$ 2	$ 2,231	$ (101,036)	$ (98,803)
Issuance of Series B redeemable convertible preferred stock, net of offering cost, expenses and discount	—	—	37,073,162	37,185	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	10,428	—	43	—	43
Stock-based compensation	—	—	—	—	—	—	264	—	264
Net loss	—	—	—	—	—	—	—	(7,412)	(7,412)
March 31, 2023	81,790,144	81,525	37,073,162	37,185	514,972	2	2,538	(108,448)	(105,908)
Issuance of common stock upon exercise of stock options	—	—	—	—	6,739	—	27	—	27
Vesting of restricted common stock	—	—	—	—	54,035	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	352	—	352
Net loss	—	—	—	—	—	—	—	(9,288)	(9,288)
June 30, 2023	81,790,144	81,525	37,073,162	37,185	575,746	2	2,917	(117,736)	(114,817)
Issuance of Series B redeemable convertible preferred stock, net of offering cost, expenses and discount	—	—	39,024,386	39,817	—	—	—	—	—
Settlement of Series B preferred stock tranche rights liability, upon issuance of milestone shares	—	—	—	8,001	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	4,229	—	32	—	32
Stock-based compensation	—	—	—	—	—	—	519	—	519
Net loss	—	—	—	—	—	—	—	(22,845)	(22,845)
September 30, 2023	81,790,144	$ 81,525	76,097,548	$ 85,003	579,975	$ 2	$ 3,468	$ (140,581)	$ (137,111)

See accompanying notes to condensed consolidated financial statements

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited, in thousands except shares)

	Seed Series 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 Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
December 31, 2023	81,790,144	$ 81,525	105,595,101	$ 121,148	119,599,872	$ 164,604	640,386	$ 2	$ 4,250	$ (153,021)	$ (148,769)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	—	—	50	—	50
Stock-based compensation	—	—	—	—	—	—	—	—	1,147	—	1,147
Net loss	—	—	—	—	—	—	—	—		(12,508)	(12,508)
March 31, 2024	81,790,144	81,525	105,595,101	121,148	119,599,872	164,604	640,386	2	5,447	(165,529)	(160,080)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	349,962		1,315	—	1,315
Vesting of restricted common stock	—	—	—	—	—	—	33,193		—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	1,038	—	1,038
Net loss	—	—	—	—	—	—	—	—	—	(17,049)	(17,049)
June 30, 2024	81,790,144	81,525	105,595,101	121,148	119,599,872	164,604	1,023,541	2	7,800	(182,578)	(174,776)
Issuance of common stock, net of offering cost, expenses and discount	—	—	—	—	—	—	20,125,000	2	332,427	—	332,429
Conversion of convertible preferred stock into common stock upon initial public offering	(81,790,144)	(81,525)	(105,595,101)	(121,148)	(119,599,872)	(164,604)	33,210,876	3	367,150	—	367,153
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	43,232	—	199	—	199
Vesting of restricted common stock	—	—	—	—	—	—	7,059	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	2,031	—	2,031
Net loss	—	—	—	—	—	—	—	—	—	(17,481)	(17,481)
September 30, 2024	–	$ –	–	$ –	–	$ –	54,409,708	$ 7	$ 709,607	$ (200,059)	$ 509,555

See accompanying notes to condensed consolidated financial statements

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (47,038)	$ (39,545)
Adjustments to reconcile net loss to cash used in operating activities:		
Change in fair value of Series B preferred stock tranche rights liability	—	13,356
Stock-based compensation	4,216	1,134
Depreciation	41	5
Non-cash lease expense	199	26
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(280)	(855)
Accounts payable and accrued expenses	728	(410)
Accounts payable and accrued expenses – related party	(2,374)	(11,296)
Operating lease liabilities	(211)	(7)
Net cash used in operating activities	(44,719)	(37,592)
Investing activities:		
Purchase of property and equipment	(31)	(150)
Proceeds from sale of property and equipment	62	—
Net cash provided by (used in) investing activities	31	(150)
Financing activities:		
Proceeds from issuance on common stock, net of issuance costs	333,479	—
Proceeds from issuance of preferred stock and preferred stock tranche rights, net	—	77,645
Proceeds from exercise of options	1,527	149
Net cash provided by financing activities	335,006	77,794
Net increase in cash and cash equivalents	290,318	40,052
Cash and cash equivalents at beginning of period	230,440	4,158
Cash and cash equivalents at end of period	$ 520,758	$ 44,210
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Settlement of Series B preferred stock tranche rights, upon issuance of milestone shares	$ —	$ 8,001
Right-of-use asset obtained in exchange for lease liability	$ —	$ 703
Vesting of early exercise stock options	$ 51	$ 51
Offering costs included in accounts payable and accrued expenses	$ 1,052	$ —
Series B preferred stock tranche rights liability, upon initial issuance of shares	$ —	$ 642

See accompanying notes to condensed consolidated financial statements

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 ficerafusp alfa 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 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 the Company’s product development efforts are successful, it is uncertain when, if ever, Bicara will realize significant revenue from product sales.

Reverse Stock Split

In September 2024, the Company’s board of directors approved an amendment to the fourth amended and restated certificate of incorporation to effect a reverse split of shares of the Company’s common stock and redeemable convertible preferred stock on a 9.2435-to-1 basis (the “Reverse Stock Split”) which was effected on September 5, 2024. The par value and authorized number of shares of common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All share data and per share data amounts for all periods presented in the condensed consolidated financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

Initial Public Offering ("IPO")

On September 13, 2024, the Company closed its IPO, pursuant to which it issued and sold an aggregate of 17,500,000 shares of its common stock at a public offering price of $18.00 per share and the Company issued and sold 2,625,000 additional shares of its common stock to the underwriters of the IPO pursuant to the full exercise of their option to purchase additional shares, resulting in net proceeds of approximately $332.4 million, after deducting underwriting discounts, commissions and other offering expenses payable by the Company, totaling $29.8 million. Immediately prior to the closing of the IPO, the Company’s outstanding redeemable convertible preferred stock automatically converted into 33,210,876 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

In connection with the closing of its IPO, on September 13, 2024, the Company’s certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.0001 per share and 10,000,000 shares of preferred stock, par value of $0.0001 per share.

The Company historically has funded its operations from the issuance of redeemable convertible preferred stock, common stock and through debt financing.

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 September 30, 2024, the Company had cash of $520.8 million and an accumulated deficit of $200.1 million.

The Company expects that its cash and cash equivalents as of September 30, 2024 of $520.8 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 unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission (SEC). 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 Company's unaudited condensed consolidated financial statements include the financial position, results of operations and cash flows of Bicara. The Company's unaudited condensed consolidated financial statements are denominated in U.S. dollars. The unaudited condensed 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.

Unaudited Interim Condensed Consolidated Financial Statements

The condensed consolidated balance sheet as of September 30, 2024, condensed consolidated statements of operations, condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) and condensed consolidated cash flows for the nine months ended September 30, 2024 and 2023 and related notes to condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The condensed consolidated results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2023 included herein was derived from the audited consolidated financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements, which were previously filed in Form S-1/A on September 11, 2024.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards; and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in total annual gross revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K), or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

Use of Estimates

The preparation of unaudited condensed 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 unaudited condensed 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 Seed Series, 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 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 6 Redeemable Convertible Preferred Stock to these condensed 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 were classified as Level 3 financial liabilities (Refer to Note 3 Fair value measurement to these unaudited condensed consolidated financial statements for more details).

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.

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.

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 three months ended September 30, 2024 and 2023, the Company incurred $15.9 million and $6.9 million, respectively, relating to research and development expenses. During the nine months ended September 30, 2024 and 2023, the Company incurred $43.7 million and $20.1 million, respectively, relating to research and development expenses. The Company recorded accrued liabilities of $9.2 million and $9.6 million for clinical trial and contract manufacturing expenses as of September 30, 2024 and December 31, 2023, 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 Company's common stock is listed on the Nasdaq Global Market and its value is determined by the market price on the Nasdaq Global Market as of the date of the grant.

Prior to the Company's IPO, the grant date fair value of stock awards granted under its 2019 Stock Option and Grant Plan were 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,* such as option-pricing method or OPM and probability weighted expected return method or PWERM. The OPM method allowed for the allocation of the Company's equity value among the various equity capital owners and considered a variety of factors, included 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. PWERM involved the estimation of future potential outcomes for the Company, as well as values and probabilities associated with each respective potential outcome which included an IPO scenario or continued operation as a private company scenario. Among other factors were 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 non-employees in a similar fashion to the way it accounts for share-based compensation awards to employees.

Comprehensive Loss

Comprehensive loss consists of net loss and certain changes in stockholders' equity that are excluded from net loss, 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 was computed using the two-class method required due to the participating securities, such securities did not participate in net losses and therefore did not impact the Company's net loss from continuing operations per share calculations.

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.

For the three and nine months ended September 30, 2024 and 2023, the following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be anti-dilutive:

	September 30,	
	2024	2023
Options and restricted stock awards outstanding	7,999,713	2,950,707
Seed Series redeemable convertible preferred stock	—	8,848,387
Series B redeemable convertible preferred stock	—	8,232,546

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 and Significant Accounting Policies

The Company reviews new accounting standards as they are issued by the FASB or other standard-setting bodies. As of September 30, 2024, the Company has not identified any new standards that it believes will have a material impact on the Company's financial statements.

Accounting Pronouncements Issued and Not Adopted as of September 30, 2024

Accounting Standards Update (ASU) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires that an entity report segment information in accordance with Topic 280, Segment Reporting. The amendment in the ASU is intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, on a retrospective basis, with early adoption permitted. The Company is currently evaluating the impact of the new standard on its unaudited condensed consolidated financial statements and disclosures.

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 cash income taxes paid. The standard largely follows the proposed ASU issued 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 unaudited condensed 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 unaudited condensed 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 September 30, 2024 and December 31, 2023 (in thousands):

Description	Level 1	Level 2	Level 3	September 30, 2024
Assets:				
Money market funds included within Cash and cash equivalent	$ 519,631	$ —	$ —	$ 519,631
Total	$ 519,631	$ —	$ —	$ 519,631

Description	Level 1	Level 2	Level 3	December 31, 2023
Assets:				
Money market funds included within Cash and cash equivalent	$ 230,088	$ —	$ —	$ 230,088
Total	$ 230,088	$ —	$ —	$ 230,088

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 of certain milestones, 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 deemed relevant.

The following table sets forth a summary of the changes in fair value of the Level 3 Series B Tranche Rights for the nine months ended September 30, 2023 (in thousands):

	Tranche Rights Liability
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	13,356
Settlement of preferred stock tranche rights	(8,001)
Balance as of September 30, 2023	$ 5,997

As of September 30, 2023, the Company recorded $6.0 million tranche rights liability within accrued expenses and other current liabilities on the balance sheet. The tranche rights liability were settled in September and November 2023.

The following assumptions were used in the estimation of the fair value of the Series B Tranche Rights, on the closing dates of Series B financing tranches and as of September 30, 2023:

	March 2, 2023 Initial Closing	September 8, 2023 Milestone Closing
Preferred share price	$ 1.01	$ 1.23
Expected term (in years)	0.5	0
Risk-free rate	5.2%	—%
Probability of achievement	95.0%	100.0%

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued research and development expenses	$ 7,448	$ 6,035
Accrued bonus and payroll related expenses	1,807	1,742
Accrued professional fees	1,087	184
Accrued other	68	92
Total	$ 10,410	$ 8,053

5. Common Stock

The Company has 500,000,000 shares of Common Stock authorized for issuance, par value $0.0001 per share, of which 54,424,994 shares issued, net of share repurchased and cancellation, and 54,409,708 shares, net were outstanding as of September 30, 2024 and 711,895 shares issued, net of share repurchased and cancellation, and 640,386 shares, net were outstanding as of December 31, 2023. The Company has reserved 5,881,181 shares of Common Stock for issuance to officers, directors, employees and consultants pursuant to the 2019 Stock Option and Grant Plan. As of December 31, 2023, of the 640,386 shares outstanding, 87,404 shares relate to the exercises of stock options, 437,203 shares relate to vesting of RSAs issued under the 2019 Stock Option and Grant Plan, 115,757 shares of Common Stock are held by Biocon Limited and its affiliates (“Biocon”) and were awarded by the Company in 2020 and the remaining balance was issued to an investor.

In September 2024, the Company completed an IPO. As part of the IPO, the Company received net proceeds of $332.4 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company, totaling $29.8 million from the issuance of 20,125,000 shares.

Prior to the IPO, the Company held shares of convertible redeemable preferred shares, which consisted of Series A, Series B and Series C of preferred stock. Each tranche was subject to automatic conversion to common stock per the terms of the initial agreement. Prior to the IPO, there were 81,790,144, 105,595,101 and 119,599,872 shares outstanding in Series A, Series B and Series C tranches of preferred stock, respectively. These shares were converted into 33,210,876 shares of common stock upon completion of the IPO.

6. Redeemable Convertible Preferred Stock

On December 23, 2020, the Company issued to Biocon 40,000,000 shares of Seed Series 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 Seed Series Preferred Stock with par value of $0.0001 per share and price of $1.00 per share. On March 2, 2023, the Company reduced the total number of its authorized Seed Series Preferred Stock to 81,790,144.

In March 2022, as part of the first close of the Company's Seed Series 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 Seed Series extension financing at $1.00 per share. On April 26, 2022, the Company issued 5,350,000 shares of Seed Series 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 Seed Series 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 Seed Series Preferred Stock held by relatives of the Chief Executive Officer.

In July 2022, as part of the second close of the Company's Seed Series extension financing, the Company sold an additional 3,000,000 shares of Seed Series 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 Seed Series 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 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 unaudited condensed 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 unaudited condensed 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.

The Seed Series 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 had 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 9.2435:1. All outstanding shares of the Preferred Stock were converted automatically into 33,210,876 shares of Common Stock immediately prior to the closing of the sale of shares of Common Stock to the public on September 13, 2024.

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 were 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 Seed Series 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.

Seed Series Preferred Stock - The Seed Series preferred stockholders shall have priority over the common stockholders, with a liquidation preference equal to the greater of (a) the Seed Series 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 Seed Series 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 Seed Series Preferred Stock the full amount to which they shall be entitled, the holders of shares of Seed Series 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 Seed Series Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

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 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 Seed Series 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 September 30, 2024.

Seed Series Preferred Stock – The Company shall not declare, pay or set aside any dividends on shares of Common Stock unless the holders of the Seed Series 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 September 30, 2024.

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 Seed Series 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.
vi. 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.

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.

7. Stock-Based Compensation

Stock Option and Grant Plans

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.

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 8,856,245 shares of Common Stock. For the period ended September 30, 2024, 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.

In 2024, in connection with the Company's IPO, the board of directors adopted, and the Company's shareholders approved the 2024 Stock Option and Grant Plan (the "2024 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.

Under the 2024 Plan, the Company is authorized to issue up to 2,453,616 shares of Common Stock, plus on January 1, and on each January 1 thereafter, the number of shares of stock reserved and available for issuance under the 2024 Plan shall automatically be cumulatively increased by 5% of the outstanding shares on the immediately preceding December 31 or such lesser number of shares as approved by the Company. Through September 30, 2024, the Company has issued 174,707 ISOs and NQSOs under the 2024 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 2024 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.

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

The Company recognized total stock-based compensation expense for non-employees and employees in its statements of operations as follows (in thousands):

	Three Months Ended September 30,	
	2024	2023
General and administrative	$ 1,469	$ 398
Research and development	562	121
Total	$ 2,031	$ 519

	Nine Months Ended September 30,	
	2024	2023
General and administrative	$ 3,172	$ 924
Research and development	1,044	210
Total	$ 4,216	$ 1,134

Restricted Stock Awards

A summary of RSA award activity for non-employees and employees of the Company is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2023	47,199	$ 4.07
Granted	—	—
Vested	(40,252)	4.07
Repurchased/forfeited	—	—
Balance as of September 30, 2024	6,947	$ 4.07

As of September 30, 2024, total unrecognized compensation costs of $0.1 million related to unvested stock-based compensation arrangements are expected to be recognized as expense over a weighted average period of 0.1 years.

Stock Options

A summary of options award activity for non-employees and employees of the Company is as follows:

	Shares	Weighted-Average Exercise Price	Weighted Average – Remaining Contractual Life (years)	Aggregate Intrinsic Value (1) (in thousands)
Outstanding as of December 31, 2023	4,850,669	$ 4.53		
Granted	3,652,807	9.13		
Exercised	(393,216)	3.97		
Canceled	(117,494)	4.01		
Outstanding as of September 30, 2024	7,992,766	6.67	9.3	$ 133,789
Exercisable as of September 30, 2024	897,774	$ 4.53	8.5	$ 16,951
Exercisable and expected to vest as of September 30, 2024	7,992,766		9.3	

(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 September 30, 2024 for the options that were in the money.

The weighted-average fair value of options granted during the nine months ended September 30, 2024 and 2023, was $6.99 and $2.77, respectively.

The Company had 7,094,992 unvested stock options outstanding as of September 30, 2024. As of September 30, 2024, total unrecognized compensation costs of $37.0 million related to unvested stock options are expected to be recognized as expense over a weighted average period of 3.3 years.

On September 5, 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective September 5, 2024. The ESPP initially reserves and authorizes the issuance of up to 507,383 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) 1,014,766 shares of common stock, (ii) 1% of the sum of (A) the number of shares of our common stock issued and outstanding on the immediately preceding December 31, and (B) the number of shares of common stock issuable pursuant to the exercise of any outstanding, pre-funded warrants to acquire such common stock for a nominal exercise price on the immediately preceding December 31, or (iii) such 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. There has been no activity on this plan to date and no stock-based compensation expense was recognized during the three months ended September 30, 2024.

8. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to losses incurred since inception and the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

9. Significant Agreements – Related Parties

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 three and nine months ended September 30, 2024 and 2023. As of September 30, 2024 and December 31, 2023, the Company owed $0.0 million and $1.6 million, respectively, which 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 three months ended September 30, 2024 and 2023, the Company incurred $0.3 million and $0.7 million research and development expenses, respectively, under the BBL Agreements. For the nine months ended September 30, 2024 and 2023, the Company incurred $1.1 million and $0.7 million research and development expenses, respectively, under the BBL Agreements. As of September 30, 2024, and December 31, 2023, the Company owed $1.1 million and $1.7 million, respectively, which were classified in accrued expenses-related party on the balance sheets.

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 three months ended September 30, 2024 and 2023 the Company incurred $2.0 million and $1.6 million of research and development expenses, respectively, under the Syngene Agreements. For the nine months ended September 30, 2024 and 2023 the Company incurred $6.3 million and $5.8 million of research and development expenses, respectively, under the Syngene Agreements. As of September 30, 2024, and December 31, 2023, the Company owed $1.2 million and $2.9 million, respectively, relating to these incurred costs, of which $0.4 million and $1.0 million, respectively, were classified in accounts payable-related party and $0.8 million and $1.9 million, 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 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. There has been immaterial interest income from the Promissory Note. The CFO repaid the full amount in June 2024. As of December 31, 2023, the Company recorded $68 thousand within prepaid expenses and other assets, and $68 thousand within other assets on the balance sheet.

10. 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 three months ended September 30, 2024 and 2023 the Company incurred $3.5 million and $2.1 million in expenses. For the nine months ended September 30, 2024 and 2023 the Company incurred $9.8 million and $5.3 million in expenses, respectively and paid $13.3 million and $8.8 million, respectively, to IQVIA. As of September 30, 2024 and December 31, 2023, the Company had $0.8 million and $1.6 million classified in accounts payable, respectively and $2.4 million and $4.7 million classified in accrued expenses and other current liabilities on the balance sheets.

11. 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 does not have contingency reserves established for any litigation liabilities as of September 30, 2024, and December 31, 2023.

12. Subsequent Events

In October, 2024, the Company amended its original lease agreement to lease an additional 4,744 square feet of office space (the "Amended Lease") in order to expand the Company's headquarters. The base rent under the Amended Lease is approximately $0.3 million per year. The Amended Lease did not extend the original lease end date under the original lease term.

On October 22, 2024, a complaint was filed in federal district court in the District of Massachusetts by Y-Trap, Inc. ("Y-Trap") naming as defendants us and Biocon LTD. ("Biocon"), captioned Y-Trap, Inc. v. Biocon LTD. and Bicara Therapeutics Inc., No. 24-cv-12678 (D. Mass.). The complaint alleges a claim for correction of inventorship of a number of patents, including patents alleged to be licensed to us relating to ficerafusp alfa. The complaint also alleges claims against defendants for unfair trade practices pursuant to Chapter 93A of the Massachusetts General Laws, unjust enrichment, and civil conspiracy. The complaint seeks, among other things, damages (including compensatory, enhanced, and punitive damages), an order correcting the inventorship of the patents at issue, costs and attorney's fees, and other equitable and injunctive relief. We intend to vigorously defend against this litigation.

Item 2. 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 as of and for three and nine months ended September 30, 2024 and 2023, and related notes and other financial information included elsewhere in the previously filed prospectus and in conjunction with our audited consolidated financial statements. This discussion and analysis and other parts of this Form 10-Q 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 Form 10-Q. You should carefully read the "Risk Factors" section of this Form 10-Q 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 ficerafusp alfa 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, ficerafusp alfa 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. Ficerafusp alfa 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. Ficerafusp alfa 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 ficerafusp alfa in combination with pembrolizumab as a first-line therapy in recurrent/metastatic, HNSCC excluding patients with HPV-positive oropharyngeal squamous cell carcinoma, or OPSCC, late in the fourth quarter of 2024 or early in the first quarter of 2025.

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 ficerafusp alfa, 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 September 30, 2024, we had raised aggregate net proceeds of $686.5 million and had cash and cash equivalents of $520.8 million.

We have incurred operating losses in each year since our inception. Our net losses were $47.0 million and $39.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $200.1 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;
- 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 ficerafusp alfa or any future product candidates for which we successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize ficerafusp alfa or any future product candidates for which we may obtain marketing approval;

- make any payments due under potential 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, manufacturing and research and development activities.

Based upon our current operating plans, we believe that our existing cash and cash equivalents will be sufficient to fund our operations into the first half of 2029. 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. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for ficerafusp alfa or future product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for ficerafusp alfa 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 ficerafusp alfa and any future product candidates we pursue. If we fail to complete clinical development of or to obtain regulatory approval for ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa. 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 ficerafusp alfa 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 ficerafusp alfa into late-stage clinical trials, (ii) develop ficerafusp alfa 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 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 both our IPO in 2024 and from sales of Series B and C redeemable convertible preferred stock in 2023.

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 three and nine months ended September 30, 2024 and 2023.

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 three months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023.

	Three Months Ended September 30,		
	2024	**2023**	**Change**
Operating Expenses:			
Research and development—related party	$ 2,310	$ 2,271	$ 39
Research and development	13,554	4,668	8,886
General and administrative	4,764	2,591	2,173
Total operating expenses	20,628	9,530	11,098
Loss from operations	(20,628)	(9,530)	(11,098)
Other income (expenses)			
Interest income	3,147	13	3,134
Change in fair value of Series B preferred stock tranche rights liability	—	(13,328)	13,328
Total other income (expenses)	3,147	(13,315)	16,462
Net loss before income taxes	(17,481)	(22,845)	5,364
Net loss	$ (17,481)	$ (22,845)	$ 5,364

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

Research and development expenses increased by $8.9 million from $6.9 million for the three months ended September 30, 2023, to $15.9 million for the three months ended September 30, 2024.

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023. (in thousands):

	Three Months Ended September 30,		
	2024	**2023**	**Change**
Research	$ 448	$ 452	$ (4)
Manufacturing and process development	7,107	2,765	4,342
Clinical operations and development	5,339	2,512	2,827
Research and development personnel cost and other (including stock-based compensation)	2,970	1,210	1,760
Total research and development expenses	$ 15,864	$ 6,939	$ 8,925

The increase in research and development expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 was primarily due to:

- approximately $4.3 million in increased manufacturing cost, driven by an increase in drug substance batch manufacturing in connection with our Phase 1/1b and our pivotal Phase 2/3 clinical trial;
- approximately $2.8 million in increased clinical operation and development cost, driven by costs associated with our pivotal Phase 2/3 clinical trial design and continued patient enrollment in our Phase 1/1b dose expansion cohorts; and
- approximately $1.8 million in increased personnel and other related costs including stock-based compensation, 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.

The table below summarizes our research and development expenses by program (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
Direct external program expenses:			
ficerafusp alfa	$ 12,895	$ 5,627	$ 7,268
BCA 300	—	37	(37)
Internal and unallocated expenses:			
Personnel related costs (including stock-based compensation)	2,860	1,197	1,663
Other	109	78	31
Total research and development expenses	$ 15,864	$ 6,939	$ 8,925

The increase in research and development expenses by program for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 was primarily due to:

- approximately $7.3 million in increased costs for our ficerafusp alfa program, driven by manufacturing costs and clinical operation and development costs associated with our pivotal Phase 2/3 clinical trial design and continued patient enrollment in our Phase 1/1b dose expansion cohorts; and
- approximately $1.7 million in increased personnel cost, 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 $2.2 million from $2.6 million for the three months ended September 30, 2023, to $4.8 million for the three months ended September 30, 2024. The following table summarizes our general and administrative expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
General and administrative personnel costs (including stock-based compensation)	$ 3,312	$ 1,539	$ 1,773
Professional fees	870	655	215
Facility costs, IT, office expense and other	582	397	185
Total general and administrative expenses	$ 4,764	$ 2,591	$ 2,173

The increase in general and administrative expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 was primarily due to:

- approximately $1.8 million in increased personnel related costs, including stock-based compensation, primarily driven by an increase in the size of our workforce and due to a higher number and value of stock options granted;
- approximately $0.2 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 operating a publicly traded company; and
- approximately $0.2 million in increased information technology expenses and related miscellaneous expenses.

Other (Expense) Income

Interest income

Interest income for the three months ended September 30, 2024 and 2023 was $3.1 million and $0.1 million, respectively. The increase was primarily due to significant increase in cash equivalents, as a result of proceeds from the IPO, Series B and Series C financings.

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

Change in fair value of Series B preferred stock tranche rights liability for the three months ended September 30, 2024 and 2023 was none and $13.3 million, respectively. The change in fair value in 2023 was due to meeting the milestone in the third quarter of 2023.

Comparison of the nine months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	**2023**	**Change**
Operating Expenses:			
Research and development—related party	$ 7,400	$ 6,511	$ 889
Research and development	36,336	13,544	22,792
General and administrative	12,016	6,147	5,869
Total operating expenses	55,752	26,202	29,550
Loss from operations			
Other (expenses) income			
Interest income	8,715	13	8,702
Change in fair value of Series B preferred stock tranche rights liability	—	(13,356)	13,356
Total other income (expense)	8,715	(13,343)	22,058
Net loss before income taxes	47,037	39,545	7,492
Income tax expense	(1)	—	(1)
Net loss	$ 47,038	$ 39,545	$ 7,493

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

Research and development expenses increased by $23.7 million from $20.1 million for the nine months ended September 30, 2023, to $43.7 million for the nine months ended September 30, 2024.

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
Research	$ 1,780	$ 1,690	$ 90
Manufacturing and process development	20,046	7,465	12,581
Clinical operations and development	15,113	8,606	6,507
Research and development personnel cost and other (including stock based compensation)	6,797	2,294	4,503
Total research and development expenses	$ 43,736	$ 20,055	$ 23,681

The increase in research and development expenses for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 was primarily due to:

- approximately $12.6 million in increased manufacturing cost, driven by an increase in drug substance batch manufacturing in connection with our Phase 1/1b and our pivotal Phase 2/3 clinical trial;
- approximately $6.5 million in increased clinical operation and development cost, driven by costs associated with our pivotal Phase 2/3 clinical trial design and continued patient enrollment in our Phase 1/1b dose expansion cohorts; and
- approximately $4.5 million in increased personnel and other related costs including stock-based compensation, 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.

The table below summarizes our research and development expenses by program (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
Direct external program expenses:			
ficerafusp alfa	$ 36,939	$ 16,773	$ 20,166
BCA 300	—	702	(702)
BCA 400/600	—	17	(17)
Internal and unallocated expenses:			
Personnel related costs (including stock-based compensation)	6,643	2,541	4,102
Other	154	22	132
Total research and development expenses	$ 43,736	$ 20,055	$ 23,681

The increase in research and development expenses by program for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 was primarily due to:

- approximately $20.2 million in increased costs for our ficerafusp alfa program, driven by manufacturing costs and clinical operation and development costs associated with our pivotal Phase 2/3 clinical trial design and continued patient enrollment in our Phase 1/1b dose expansion cohorts; and
- approximately $4.1 million in increased personnel cost, 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;

These increases were partially offset by approximately $0.7 million in decreased costs for our BCA 300 program, which was paused in 2023.

General and Administrative Expenses

General and administrative expenses increased by $5.9 million from $6.1 million for the nine months ended September 30, 2023, to $12.0 million for the nine months ended September 30, 2024. The following table summarizes our general and administrative expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
General and administrative personnel costs (including stock-based compensation)	$ 8,127	$ 3,977	$ 4,150
Professional fees	2,463	807	1,656
Facility costs, IT, office expense and other	1,426	1,363	63
Total general and administrative expenses	$ 12,016	$ 6,147	$ 5,869

The increase in general and administrative expenses for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 was primarily due to:

- approximately $4.2 million in increased personnel related costs, including stock-based compensation, primarily driven by an increase in the size of our workforce and related number and value of stock options granted;
- approximately $1.7 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 operating a publicly traded company; and
- approximately $0.1 million in increased information technology expenses and related miscellaneous expenses.

Other (Expense) Income

Interest income

Interest income for the nine months ended September 30, 2024 and 2023 was $8.7 million and $0.1 million, respectively. The increase was primarily due to significant increase in cash equivalents, as a result of proceeds from the IPO, Series B and Series C financings.

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

Change in fair value of Series B preferred stock tranche rights liability for the nine months ended September 30, 2024 and 2023 was none and $13.4 million, respectively. The change in fair value in 2023 was due to the meeting of the milestone in the third quarter of 2023.

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 ficerafusp alfa or any future product candidates we elect to pursue. From our inception in December 2018 through September 30, 2024, we have received aggregate net proceeds of $686.5 million from the sale of our redeemable convertible preferred stock in private placements, sale of common stock and debt financing.

In September 2024, the Company completed an initial public offering, or IPO. As part of the offering, the Company received net proceeds of $332.4 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company, totaling $29.8 million from the issuance of 20,125,000 shares.

Future Funding Requirements

As of September 30, 2024, we had cash and cash equivalents of $520.8 million, which based upon our current operating plans, we believe will be sufficient to fund our operations into the first half of 2029. 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 ficerafusp alfa and future product candidates;
- the costs and timing of manufacturing for ficerafusp alfa and any future product candidates and commercial manufacturing thereof;
- the costs, timing, and outcome of regulatory review of ficerafusp alfa 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 ficerafusp alfa 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 Nine Months Ended September 30, 2024 and 2023

The following table sets forth a summary of the net cash flow activity for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	**2023**
Cash used in operating activities	$ (44,719)	$ (37,592)
Cash provided by (used in) investing activities	31	(150)
Cash provided by financing activities	335,006	77,794
Net increase in cash and cash equivalents	$ 290,318	$ 40,052

Operating Activities

For the nine months ended September 30, 2024, net cash used in operating activities was $44.7 million resulting from our net loss of $47.0 million and decreases in our operating assets and liabilities of $2.1 million, partially offset by non-cash charges of $4.5 million, consisting of stock-based compensation expense, depreciation and non-cash lease expense.

For the nine months ended September 30, 2023, net cash used in operating activities was $37.6 million resulting from our net loss of $39.5 million and net outflows in our operating assets and liabilities of $12.6 million, partially offset by non-cash charges of $14.5 million. Non-cash charges consisted of stock-based compensation expense, depreciation and changes in fair value of Series B preferred stock tranche rights liability.

Investing Activities

Net cash provided by investing activities was insignificant for the nine months ended September 30, 2024 and net cash spent was $0.2 million for the nine months ended September 30, 2023, due to purchases of new equipment for the Company's new office space.

Financing Activities

Net cash provided by financing activities was $335.0 million during the nine months ended September 30, 2024, consisting of $333.5 million in net proceeds from issuance of common stock in its IPO and $1.5 million in proceeds from the exercise of stock options. Offering costs of $1.1 million remain in accounts payable and accrued expenses as of September 30, 2024 and will be offset against net financing fees received upon payment.

Net cash provided by financing activities was $77.8 million during the nine months ended September 30, 2023, consisting of $77.7 million in net proceeds from the issuance of preferred stock and preferred stock tranche rights, in connection with Series B financing and $0.1 million in proceeds from the exercise of stock options.

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 Polices 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 U.S., 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 the previously filed Form S-1/A, 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 prior to September 2024, 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.

Prior to the IPO our common stock valuations were prepared using (i) the back-solve method to calculate the total equity value and the option-pricing method, or OPM, to allocate the total equity value and (ii) probability weighted expected return method or PWERM. 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.

The PWERM method involved the estimation of future potential outcomes for the Company, as well as values and probabilities associated with each respective potential outcome. The common stock per share value determined using this approach was ultimately based upon probability-weighted per share values resulting from the various future scenarios, which included an IPO scenario or continued operation as a private company scenario.

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 8 titled *"Stock-based Compensation"* to our unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q 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 nine months ended September 30, 2024, and 2023, respectively. Stock-based compensation totaled $4.2 million and $1.1 million for the nine months ended September 30, 2024, and 2023, respectively.

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 Form 10-Q; (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 our IPO; (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 Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer, Treasurer), has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. On October 22, 2024, a complaint was filed in federal district court in the District of Massachusetts by Y-Trap, Inc. ("Y-Trap") naming as defendants us and Biocon LTD. ("Biocon"), captioned Y-Trap, Inc. v. Biocon LTD. and Bicara Therapeutics Inc., No. 24-cv-12678 (D. Mass.). The complaint alleges a claim for correction of inventorship of a number of patents, including patents alleged to be licensed to us relating to ficerafusp alfa. The complaint also alleges claims against defendants for unfair trade practices pursuant to Chapter 93A of the Massachusetts General Laws, unjust enrichment, and civil conspiracy. The complaint seeks, among other things, damages (including compensatory, enhanced, and punitive damages), an order correcting the inventorship of the patents at issue, costs and attorney's fees, and other equitable and injunctive relief. We intend to vigorously defend against this litigation.

Item 1A. 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 Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 revenue, obtain regulatory approval, 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, and $47.0 million for the nine months ended September 30, 2024. As of September 30, 2024, 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, ficerafusp alfa.

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

- advance ficerafusp alfa through clinical development;
- seek regulatory approvals for ficerafusp alfa 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 ficerafusp alfa and any future product candidate;
- 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.

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, ficerafusp alfa. Even if ficerafusp alfa 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 ficerafusp alfa, 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 and September 30, 2024, we had $230.4 million and $520.8 million of cash and cash equivalents, respectively. Based upon our current operating plan, we believe that our existing cash and cash equivalents 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 our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2029. 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 ficerafusp alfa. 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 ficerafusp alfa or any future product candidates;
- the number of clinical trials required for regulatory approval of ficerafusp alfa or future product candidates;
- the costs, timing and outcome of regulatory review of ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa, 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, 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 ficerafusp alfa.

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 our initial public 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 ficerafusp alfa. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize ficerafusp alfa, 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 ficerafusp alfa remains in clinical or preclinical development. Our future success and ability to generate revenue from ficerafusp alfa is dependent on our ability to successfully develop and commercialize ficerafusp alfa 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 ficerafusp alfa if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, ficerafusp alfa, including:

- our inability to demonstrate to the satisfaction of the FDA, Health Canada, EMA or other comparable regulatory authorities that ficerafusp alfa 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 ficerafusp alfa 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. ficerafusp alfa 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 ficerafusp alfa. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than ficerafusp alfa or, in the case of drugs, have a better safety profile than ficerafusp alfa. 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, ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa. Even if ficerafusp alfa 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, ficerafusp alfa, is initially being developed in HNSCC. We intend to initiate a pivotal Phase 2/3 trial of ficerafusp alfa 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 U.S., 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 U.S., 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 ficerafusp alfa 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 ficerafusp alfa, 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 ficerafusp alfa or Future Product Candidates

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

We are early in our development efforts as ficerafusp alfa 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, ficerafusp alfa, 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 U.S., 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 ficerafusp alfa 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 ficerafusp alfa and any future product candidates;
- our ability to complete preclinical studies for ficerafusp alfa 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 fall behind our competitors, experience significant delays or an inability to obtain regulatory approvals or commercialize ficerafusp alfa or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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;
- 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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, ficerafusp alfa 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.

Ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If ficerafusp alfa 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;
- 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 ficerafusp alfa 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 and available clinical sites or patients;
- delays in, inability, or failure to add new clinical trial sites;
- 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. It is also likely that we may compete with competitors developing product candidates in the same therapeutic areas for clinical trial sites. 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 of 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 in the future may depend on other third-party collaborators for the discovery, development and commercialization of ficerafusp alfa 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;
- collaboration agreements may restrict our right to independently pursue new product candidates; and
- the mutual termination of the Contract Transfer and License Agreement with Biocon could delay the commercialization of ficerafusp alfa.

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 ficerafusp alfa 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 ficerafusp alfa, 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 government 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 have the effect of restricting 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 most recent version of the BIOSECURE Act introduced in the House of Representatives names WuXi Bio as a "biotechnology company of concern." The most recent version of the BIOSECURE Act introduced in the House of Representatives also includes a grace period that would restrict the applicability of the BIOSECURE Act's prohibitions to existing contractual arrangements with named "biotechnology companies of concern" until 2032. If approved in this form, the BIOSECURE Act would likely not prevent us from sourcing drug product from WuXi Bio for use in clinical development. However, depending on the final language of the BIOSECURE Act, and how the law is interpreted by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or government reimbursement for our products in the future if we enter long-term commercial arrangements with WuXi Bio or other suppliers or partners identified as "biotechnology companies of concern" that extend beyond this grace period. 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 evolving regulatory and legal requirements in China, or due to the deterioration of the geo-political relationship between China and the U.S., including but not limited to potential sanctions imposed by the U.S. government on WuXi Bio, or other companies in China on whom we might rely, or any of the other countries in which our products are manufactured or 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 U.S. until we or the future collaborator receives regulatory approval of a BLA, from the FDA. It is possible that ficerafusp alfa or any future product candidates will not obtain regulatory approval from the FDA, Health Canada, the EMA or comparable foreign regulatory authorities.
Ficerafusp alfa 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;
- ficerafusp alfa may not appear to offer benefits over current therapies; or
- the quality or stability of ficerafusp alfa 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 ficerafusp alfa in combination with pembrolizumab as a treatment for HNSCC and SCAC, and may develop ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa, 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 ficerafusp alfa 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 U.S. 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.

In the future, we may also seek approval of potential product candidates 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 potential future 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. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as IMM. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. 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. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication be submitted to the Agency for review. There can be no assurance that FDA would allow any of the potential future product candidates we may develop to proceed on an accelerated approval pathway, and even if 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.

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 U.S., or a patient population of greater than 200,000 individuals in the U.S. but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. 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 ficerafusp alfa 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 U.S.—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 ficerafusp alfa 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.
Ficerafusp alfa and any future product candidates may not be commercially successful. Even if ficerafusp alfa 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 ficerafusp alfa 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 anymore established products;
- the indications for which ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 U.S. 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 ficerafusp alfa 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 U.S. 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 ficerafusp alfa and any future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of ficerafusp alfa and any future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of ficerafusp alfa 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 U.S., 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 ficerafusp alfa if we obtain regulatory approval, which may adversely affect our ability to generate revenues.

Given the development stage of ficerafusp alfa, we have no experience in sales, marketing and distribution of biotech products. However, if ficerafusp alfa 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 ficerafusp alfa which would adversely affect our business, financial condition, and ability to generate product revenues.

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

If ficerafusp alfa is approved by the FDA, we may only promote or market ficerafusp alfa in a manner consistent with its FDA-approved labeling. We will train our marketing and sales force against promoting ficerafusp alfa for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using ficerafusp alfa off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. Furthermore, the use of ficerafusp alfa for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa, including ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa.

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 ficerafusp alfa will issue in the U.S. 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 ficerafusp alfa 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, scope, inventorship, or ownership of such patents, which may result in the patent claims being narrowed, invalidated, held unenforceable, or unavailable to us. 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 U.S. 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 U.S. 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 U.S. and other countries may permit others to use our discoveries or to develop and commercialize ficerafusp alfa 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 ficerafusp alfa in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. could be less extensive than those in the U.S., assuming that rights are obtained in the U.S. 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 U.S. 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 U.S. These products may compete with ficerafusp alfa 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 ficerafusp alfa 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, circumvented, or otherwise encumbered by a third party. 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. For example, in October 2024, a complaint was filed in federal court, which among other things, alleges a claim for correction of inventorship of a number of patents, including patents alleged to be licensed to us relating to ficerafusp alfa. 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 ficerafusp alfa 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 ficerafusp alfa or other technology, the defendant could counterclaim that our patent is invalid and/or unenforceable, which is commonplace in patent litigation in the U.S. 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa, irrespective of the merits of any such allegation, for example in August 2024, we received a letter alleging ficerafusp alfa infringes certain third party patents. For example, in October 2024, a complaint was filed in federal court, which among other things, alleges a claim for correction of inventorship of a number of patents, including patents alleged to be licensed to us relating to ficerafusp alfa. 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 ficerafusp alfa. 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 ficerafusp alfa 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 U.S., 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 ficerafusp alfa to market and be precluded from manufacturing or selling ficerafusp alfa.

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 U.S. and abroad that is relevant to or necessary for the commercialization of ficerafusp alfa 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 U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market ficerafusp alfa. 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 U.S. 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 ficerafusp alfa 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 ficerafusp alfa.

We have rights, through patents that we have in-licensed or own, to the intellectual property to develop ficerafusp alfa. 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 ficerafusp alfa, 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 ficerafusp alfa, our business may be materially harmed.

Patents typically have a limited lifespan. In the U.S., 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 ficerafusp alfa 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 ficerafusp alfa, 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 ficerafusp alfa, 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 ficerafusp alfa. 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 ficerafusp alfa.

We face an inherent risk of product liability exposure related to the testing of ficerafusp alfa 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 ficerafusp alfa, 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 ficerafusp alfa 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 ficerafusp alfa 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 U.S., 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 ficerafusp alfa 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 U.S. 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 ficerafusp alfa 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 U.S. 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 U.S. or abroad. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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 ficerafusp alfa, if approved, or any future product candidates and may adversely affect the prices we may set.

In the U.S. 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 U.S., 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 U.S., 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa.

The process of manufacturing product therapeutics and bispecifics, including ficerafusp alfa, 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 ficerafusp alfa 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 ficerafusp alfa, completion of our planned clinical trials or the commercialization of ficerafusp alfa.

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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa or any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to Ownership of Our Common Stock

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 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 Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment, completion or results of our current or future preclinical and clinical trials for ficerafusp alfa;
- any delay in identifying and advancing a clinical candidate for our other programs;
- any delay in our regulatory filings for ficerafusp alfa 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 ficerafusp alfa 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 ficerafusp alfa, 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 ficerafusp alfa, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to ficerafusp alfa 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 ficerafusp alfa 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. 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 ficerafusp alfa 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 ficerafusp alfa, 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;
- the timing and success or failure of preclinical studies and clinical trials for ficerafusp alfa or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for ficerafusp alfa 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 ficerafusp alfa from regulatory authorities in the U.S. and internationally;
- exchange rate fluctuations;
- coverage and reimbursement policies with respect to ficerafusp alfa, if approved, and potential future drugs that compete with our products; and
- the level of demand for ficerafusp alfa, 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. 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 September 30, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our common stock. 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 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.

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.

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 and amended and restated bylaws 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;
- 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 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 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 the 2024 presidential election in the United States, 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 ficerafusp alfa, 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 ficerafusp alfa and other third parties for the manufacture of ficerafusp alfa 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 ficerafusp alfa 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. We could be an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in total annual gross revenue. (ii) the date we qualify as a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. 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 Quarterly Report on Form 10-Q;
- 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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. We are subject to the reporting requirements of the Exchange Act, which 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 the fifth anniversary of our initial public 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. We have started 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 beginning with the Form 10-Q for the nine months ending September 30, 2024. 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 our 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.

We are 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/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.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

Recent Sales of Unregistered Securities

During the period between July 1, 2024 and September 30, 2024, we issued to certain of our employees and officers options to purchase an aggregate of 3,240,096 shares of our common stock under our 2019 Stock Option and Grant Plan (the "2019 Plan") at a weighted-average exercise price of $9.24 per share. During this period, 43,244 shares of common stock were issued upon the exercise of options pursuant to the 2019 Plan. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transaction by an issuer not involving a public offering. On September 13, 2024, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Use of Proceeds from Registered Securities

On September 12, 2024, the SEC declared effective our registration statement on Form S-1 (File No. 333-281722), as amended, filed in connection with our IPO, or the Registration Statement. Pursuant to the Registration Statement, we registered the offer and sale of 20,125,000 shares of our common stock with a proposed maximum aggregate offering price of approximately $362,000,000. Morgan Stanley & Co. LLC, TD Securities (USA) LLC, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated acted as representatives of the underwriters for the offering. On September 16, 2024, we issued and sold 20,125,000 shares of our common stock at a price to the public of $18.00 per share, including the exercise in full by the underwriters of their option to purchase 2,626,000 shares of Common Stock. Upon completion of the IPO on September 16, 2024, we received net proceeds of approximately $336.9 million, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us of $4.5 million.

We are holding a significant portion of the balance of the net proceeds in money market funds. There has been no material change in the planned proceeds from our IPO, as described in our final prospectus filed with the SEC on September 13, 2024 pursuant to Rule 424(b) under the Securities Act.

The offering terminated after the sale of all securities registered pursuant to the Registration Statement. There has been no material change in the expected use of the net proceeds from our IPO as described in the final prospectus dated September 12, 2024 and filed with the SEC on September 13, 2024, pursuant to Rule 424(b)(4) (File No. 333-281722) of the Securities Act.

Issuer Repurchases of Equity Securities
Not applicable.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.

(c) ***Director and Officer Trading Plans and Arrangements***

None of our directors or “officers,” as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Fifth Amended and Restated Certificate of Certificate of Incorporation of the Registrant ((incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-42271) filed on September 16, 2024).
3.2	Third Amended and Restated Bylaws of the Registrant ((incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-42271) filed on September 16, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1/A (File No. 333-281722) filed on September 11, 2024).
10.1#	2024 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-281722) filed on September 11, 2024).
10.2#	2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-281722) filed on September 11, 2024).
10.3#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1/A (File No. 333-281722) filed on September 11, 2024).
10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-281722) filed on September 11, 2024).
10.5#	Form of Executive Employment Agreement (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-281722) filed on September 11, 2024).
10.6#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-281722) filed on September 11, 2024).
10.7*	Office Lease Agreement by and between Columbia Property Trust, Inc. and the Registrant, dated as of October 1, 2024.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

*	Filed herewith.
**	The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.
#	Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Bicara Therapeutics Inc.

Date: November 12, 2024	By:	/s/ Claire Mazumdar
		Claire Mazumdar
		Chief Executive Officer
		(Principal Executive Officer)
Date: November 12, 2024	By:	/s/ Ivan Hyep
		Ivan Hyep
		Chief Financial Officer
		(Principal Financial Officer)

FIRST AMENDMENT TO OFFICE LEASE AGREEMENT

THIS FIRST AMENDMENT TO OFFICE LEASE AGREEMENT (this "***Amendment***") is made as of September 24, 2024 (the "***Effective Date***"), by and between **COLUMBIA REIT – 116 HUNTINGTON, LLC**, a Delaware limited liability company ("***Landlord***"), and **BICARA THERAPEUTICS INC.**, a Delaware corporation ("***Tenant***").

RECITALS

R-1. Landlord and Tenant entered into that certain Office Lease Agreement dated as of August 16, 2023 (the "***Existing Lease***") pursuant to which Landlord is leasing to Tenant and Tenant is leasing from Landlord certain office space (the "***Existing Premises***") deemed to contain 4,617 square feet of rentable area located on a portion of the seventh (7th) floor of the Building. The Building is located at 116 Huntington Avenue, Boston, Massachusetts 02116.

R-2. Landlord and Tenant desire to amend the Lease to (i) provide for the addition to the Existing Premises of certain additional space deemed to contain 4,744 square feet of rentable area located on a portion of the seventh (7th) floor of the Building, as depicted on the diagram attached hereto as Exhibit A (the "***Expansion Space***"), and (ii) otherwise amend the Lease, subject to and in accordance with the terms and conditions set forth in this Amendment.

R-3. Except as otherwise defined in this Amendment, all terms and phrases used in this Amendment that are defined in the Lease shall have the same meaning as set forth in the Lease. In the event of any conflict between the Lease and this Amendment, the terms of this Amendment shall control. "***Lease***," as used herein, shall be deemed to refer to the Existing Lease as amended by this Amendment.

COVENANTS

NOW, THEREFORE, in consideration of the sum of Ten Dollars ($10.00) cash in hand paid, the mutual covenants hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Recitals. The foregoing Recitals are true and correct and are incorporated herein by this reference:

2. Expansion Space.

(a) Description. Landlord and Tenant hereby agree to add the Expansion Space to the Existing Premises as of the Expansion Space Commencement Date (defined below). As of the Expansion Space Commencement Date, the entire Premises shall be deemed to contain 9,361 rentable square feet comprised of a portion of the seventh (7th) floor of the Building (i.e., the Existing Premises and the Expansion Space). Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the Expansion Space upon the terms and conditions of this

Amendment. On the Expansion Space Commencement Date, the Expansion Space shall become part of the Premises and, except as otherwise provided below, be subject to all the terms and

conditions of the Lease. From and after the Expansion Space Commencement Date, the Existing Premises, together with the Expansion Space, shall be collectively referred to as the "***Premises***."

(b) Condition. Except for Landlord's Work (hereinafter defined in Exhibit B), the Expansion Space will be delivered to Tenant and are being leased "AS IS" and "WITH ALL FAULTS," and Landlord makes no representation or warranty of any kind, expressed or implied, with respect to the condition of the Expansion Space (including habitability, suitability, or fitness for a particular purpose). TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, LANDLORD HEREBY DISCLAIMS, AND TENANT WAIVES THE BENEFIT OF, ANY AND ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF HABITABILITY, SUITABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Landlord
is under no obligation to make any Alterations, repairs, or the like in or to the Expansion Space (except for Landlord's Work), the Existing Premises, the Building, or any systems serving the same on account of this Amendment.

(c) FF&E. The Expansion Space contains certain fixtures (including so-called trade fixtures), furniture, and equipment (the "FF&E"), as more specifically described on Exhibit C annexed hereto and made a part hereof. Landlord has made no representations or warranties whatsoever as to the condition of the FF&E. Tenant has examined the FF&E and accepts same in its "as-is" condition in all respects. Tenant shall neither sell nor transfer any portion of the FF&E. Tenant shall repair and maintain the FF&E throughout the Lease Term, at its sole cost and expense. Tenant shall neither replace any of the FF&E nor add any improvements to the FF&E, without Landlord's prior written approval. Tenant shall make all approved replacements and improvements at its sole cost and expense. Upon the expiration or sooner termination of this Lease, Tenant shall return the FF&E, and all replacements and improvements thereto, if any, to Landlord in good order and condition (normal wear and tear excepted). Tenant shall be solely responsible and liable for any damage done to all or any portion of the FF&E by Tenant, its agents, employees, contractors, invitees, or licensees.

3. Expansion Space Commencement Date. The "***Expansion Space Commencement Date***" shall be October 1, 2024. Notwithstanding the foregoing, Tenant shall not have any right to commence beneficial use of the Expansion Space unless the same are vacant and delivered to Tenant by Landlord. The Term for the Expansion Space shall commence on the Expansion Space Commencement Date and continue through the Expiration Date such that the Lease for all the Premises (i.e., as expanded pursuant to this Amendment) shall expire on the Expiration Date. From and after the Expansion Space Commencement Date (subject to the Expansion Space Abatement Period, defined below), Tenant shall pay Base Rent and additional rent for the Expansion Space in equal monthly installments in advance on the first day of each month during the Lease Term without setoff, deduction, or demand, and otherwise in accordance with the terms of the Lease.

4. Access Period. The Move In Period means the period commencing on September 1, 2024 and continuing through September 30, 2024; provided that no access to the Expansion Space shall be permitted unless Tenant shall deliver to Landlord written evidence specifying that Tenant is then carrying all insurance required by the Lease. Provided no Event of Default by

Tenant has occurred under the Lease, Tenant shall have the right to install in the Expansion Space, during the Move In Period only, Tenant's Cabling and other furniture, furnishings,

inventory, equipment, or trade fixtures, subject to all applicable terms and conditions of the Lease. Any and all activity by Tenant or any Agent of Tenant prior to the Expansion Space Commencement Date shall be coordinated with Landlord and its general contractor to ensure that such activity does not, to more than a de minimis extent, interfere with Landlord's Work. If Landlord determines that any such interference is occurring to more than a de minimis extent, then Landlord shall have the right to require the removal of the offending party from the Expansion Space (with Tenant having no right to assert that the Expansion Space Commencement Date or Tenant's other obligations are affected thereby). Notwithstanding anything in this Lease to the contrary: (a) Landlord shall have no responsibility with respect to any items placed in the Expansion Space by Tenant or any Agent of Tenant prior to the Expansion Space Commencement Date; and (b) all of the provisions of the Lease (including all insurance, indemnity and utility provisions) shall apply during the Move In Period, except that during such period (i) Tenant shall not be obligated to pay Base Rent and (ii) Landlord shall not be obligated to provide any utility, service or other item in excess of those customarily provided to or for the benefit of a premises in order for Landlord to perform its building standard initial improvement work thereto.

5. Monetary Provisions.

(a) Expansion Space Base Rent. The Base Rent payable with respect to the Expansion Space during the Term shall be as follows:

Start Date	End Date	Rate Per Rentable Square Foot	Annually*	Monthly
October 1, 2024**	September 30, 2025	$64.00	$303,615.96	$25,301.33
October 1, 2025	February 28, 2026	$64.00	$303,615.96	$25,301.33
*Based on twelve (12) calendar months. **Subject to abatement during the Abatement Period as set forth below.				

(b) Expansion Space Abatement. Notwithstanding the foregoing, provided no Event of Default by Tenant has occurred under the Lease, Landlord grants to Tenant an abatement of the Base Rent otherwise payable hereunder for the Expansion Space during the month of October of 2024 (the "***Expansion Space Abatement Period***"). Concurrently with Tenant's execution of this Amendment, Tenant shall pay an amount equal to one (1) monthly installment of Base Rent payable for the Expansion Space, which amount shall be credited toward the monthly installment of Base Rent payable after expiration of the Expansion Space Abatement Period.

(c) Additional Rent. The Operating Charges Base Year for the Expansion Space shall be calendar year 2025. The Real Estate Taxes Base Year for the Expansion Space shall be July 1, 2024 through June 30, 2025 (i.e., the City of Boston Fiscal Year 2025). From and after October 1, 2025, Tenant shall pay as additional rent for the Expansion Space, Tenant's

Proportionate Share of the amount by which (i) Operating Charges for each calendar year falling entirely or partly within the Lease Term exceed the Operating Charges Base Amount (i.e., the

Operating Charges incurred during the Operating Charges Base Year for the Expansion Space), and (ii) the Real Estate Taxes for each calendar year falling entirely or partly within the Lease Term exceed the Real Estate Taxes Base Amount (i.e., the Real Estate Taxes incurred during the Real Estate Taxes Base Year for the Expansion Space). Tenant's Proportionate Share for the Expansion Space shall be 1.74% for each of Operating Charges and Real Estate Taxes. With respect to the Existing Premises, Tenant shall continue to pay all items of Base Rent and additional rent in accordance with the terms of the Existing Lease.

(d) Deposit. Concurrently with Tenant's execution of this Amendment, Tenant shall pay an amount equal to one (1) monthly installment of Base Rent payable for the Expansion Space, which amount shall be credited toward the monthly installment of Base Rent payable for the Expansion Space following the end of the Expansion Space Abatement Period.

6. Renewal Term. Landlord hereby grants to Tenant the conditional right, exercisable at Tenant's option, to renew the Lease Term, with respect to all of the Premises, for one (1) term of three (3) years (the "***Renewal Term***"). If exercised, and if the conditions applicable thereto have been satisfied, the Renewal Term shall commence immediately following the Expiration Date. The right of renewal herein granted to Tenant shall be subject to, and shall be exercised in accordance with, the following terms and conditions:

(a) Tenant shall exercise its right of renewal with respect to the Renewal Term by giving Landlord written notice (the "***Renewal Option Notice***") of such election not earlier than fifteen (15) months nor later than twelve (12) months prior to the expiration of the then-current Lease Term. The parties shall then have thirty (30) days after Landlord's timely receipt of such notice (the "***Negotiation Period***") in which to agree on the annual base rent, escalation factor and additional rent which shall be payable during the Renewal Term. The parties shall attempt in good faith to agree upon an annual base rent payable for the first year of the Renewal Term and an escalation factor for which would equal one hundred percent (100%) of the applicable fair market rent taking into account all relevant factors; provided, however that consideration shall be given to the savings to Tenant resulting from its remaining in the Premises (e.g., no moving or related costs), and no consideration shall be given to (and the fair market rent so determined shall not be reduced on account of) "downtime" that may be associated with this or comparable transactions. If during the Negotiation Period the parties agree on such annual base rent, escalation factor and additional rent, then they shall promptly execute an amendment to the Lease stating the terms so agreed upon. If during the Negotiation Period the parties are unable, for any reason whatsoever, to agree on such annual base rent, escalation factor and additional rent payable, then within five (5) business days after the last day of the Negotiation Period, the parties shall each appoint a real estate broker who shall be licensed in Massachusetts and who specializes in the field of commercial office space leasing in the Building's submarket, has at least ten (10) years of experience and is recognized within the field as being reputable and ethical. Such two individuals shall each determine, within ten (10) business days after their appointment, such annual base rent, escalation factor and additional rent. If such individuals do not agree on such items, then the two individuals shall, within five (5) business days, render separate written reports of their determinations and together appoint a third similarly qualified individual. The third individual shall, within ten (10) business days after his or her appointment,

select either Landlord's broker's determination or Tenant's broker's determination (this being the third broker's sole function) as being closest to the applicable fair market annual base rent,

escalation factor and additional rent and shall notify the parties of such selection. The third broker's decision shall be final and conclusive, and binding on Landlord and Tenant. Landlord and Tenant shall each bear the cost of its broker and shall share equally the cost of the third broker. Upon determination of the annual base rent, escalation factor and concessions payable pursuant to this Section, the parties shall promptly execute an amendment to the Lease stating the rent and additional terms so determined.

(b) If the Renewal Option Notice is not given timely, then Tenant's right of renewal with respect to the Renewal Term shall lapse and be of no further force or effect.

(c) If an Event of Default by Tenant exists on the date Tenant sends its Renewal Option Notice or any time thereafter until the Renewal Term is to commence, then, at Landlord's election, the Renewal Term shall not commence and the term of this Lease shall expire at the expiration of the Lease Term.

(d) If at any time fifty percent (50%) or more of the square feet of rentable area of the entire Premises has been subleased or assigned, or if the Lease has been terminated with respect to such portion of the Premises, then Tenant's rights pursuant to this Section shall lapse and be of no further force or effect.

(e) Tenant's right of renewal under this Section may be exercised only by Tenant and may not be exercised by or for the benefit of any other transferee, sublessee, or assignee of Tenant.

(f) The Renewal Term may be exercised only with respect to all of the then- current Premises.

7. Security Deposit. Simultaneously with Tenant's execution of this Amendment, Tenant shall deposit with Landlord the amount of $25,301.33 and such amount shall be added to the security deposit held by Landlord under the Lease and the same shall be subject to all terms and conditions of the Lease applicable to the security deposit. Based on the foregoing, the Security Deposit Amount is hereby revised to be $125,301.33.

8. Brokerage. Landlord and Tenant each warrant to the other that in connection with this Amendment it has not employed or dealt with any broker, agent, or finder, other than Cushman & Wakefield U.S., Inc. (the "***Landlord's Broker***") and Cresa ("***Tenant's Broker***"). Landlord's Broker and Tenant's Broker are collectively referred to as the "***Broker***." 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.

9. Ratification. Except as otherwise expressly modified by the terms of this

Amendment, the Lease shall remain unchanged and continue in full force and effect. All terms, covenants and conditions of the Lease not expressly modified herein are hereby confirmed and ratified and remain in full force and effect, and as further amended hereby, constitute valid and binding obligations of Tenant enforceable according to the terms thereof. Nothing contained herein shall be deemed to waive any sums due from Tenant to Landlord or from Landlord to Tenant, or any default or event which, with the passage of time or delivery of notice, or both, would constitute an Event of Default under the Lease as of the date hereof. Tenant acknowledges Landlord is not in default in the performance of any of its obligations under the Lease and Tenant is unaware of any condition or circumstance which, but for the passage of time or delivery of notice, or both, would constitute a default by Landlord under the Lease. Tenant has no claims, defenses or set offs of any kind to the performance of Tenant's obligations and duties under the Lease.

10. Authority. Tenant and the person executing and delivering this Amendment 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 Delaware and the Laws of the jurisdiction in which the Building is located, and has the power and authority to enter into this Amendment, and that all action required to authorize Tenant and such person to enter into this Amendment has been duly taken.

11. Binding Effect. This Amendment shall not be effective and binding unless and until fully executed and delivered by each of the parties hereto.

12. Counterparts. This Amendment may be executed in multiple counterparts, each of which shall be an original, but all of which shall constitute one and the same Amendment. Signatures transmitted by facsimile machine, electronically or signatures transmitted via e-mail in a "PDF" format may be used in place of original signatures on this Amendment. Each party intends to be bound by such party's facsimile or "PDF" format or DocuSign or other electronic signature on this Amendment, is aware that the other parties are relying on such party's facsimile or "PDF" format or DocuSign or other electronic signature, and hereby waives any defenses to the enforcement of this Amendment based upon the form of signature.

13. Entire Agreement. This Amendment contains and embodies the entire agreement of the parties hereto with respect to the amendment of the Lease, and supersedes and revokes all negotiations, arrangements, letters of intent, representations, inducements, or other agreements, oral or in writing. No representations, inducements, or agreements, oral or in writing, between the parties not contained in this Amendment shall be of any force or effect. If any part of this Amendment is illegal or unenforceable, such part or parts of this Amendment shall be of no force or effect, and this Amendment shall be treated as if such part or parts had not been inserted. Except as otherwise provided herein, the terms and conditions of this Amendment shall inure to the benefit of and be binding upon the parties hereto and their respective successors or assigns; provided however, the foregoing shall not be deemed to amend the assignment and subletting provisions in the Lease. Landlord and Tenant each hereby covenant and agree that each provision of this Amendment has been jointly and mutually negotiated and authorized by both

Landlord and Tenant, and in the event of any dispute arising out of any provision of this Amendment, Landlord and Tenant do hereby waive any claim of authorship against the other

party.

[Signature page follows]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Amendment to be executed under seal as of the Effective Date.

LANDLORD:

COLUMBIA REIT – 116 HUNTINGTON, LLC,
a Delaware limited liability company

By: Chaperone Portfolio Mezz B LLC,
a Delaware limited liability company, its sole member

By: Columbia Property Trust Operating Partnership, L.P., a Delaware limited partnership, its sole member

By: Columbia Property Trust, Inc.,
Signed by:
Maria Blake
EBA7318D6A174B9...
a Maryland corporation, its general partner

By: Name: Maria Blake

\\4126-2912-5458 v3

_____Title: Vice President

TENANT:

DocuSigned by:
Ryan Cohlhepp
5FECFD8EDF88477...

BICARA THERAPEUTICS INC., a Delaware corporation

By: __ [SEAL]

Name: Ryan Cohlhepp

Title: Chief Operating Officer

EXHIBIT A

PLAN SHOWING THE EXPANSION SPACE

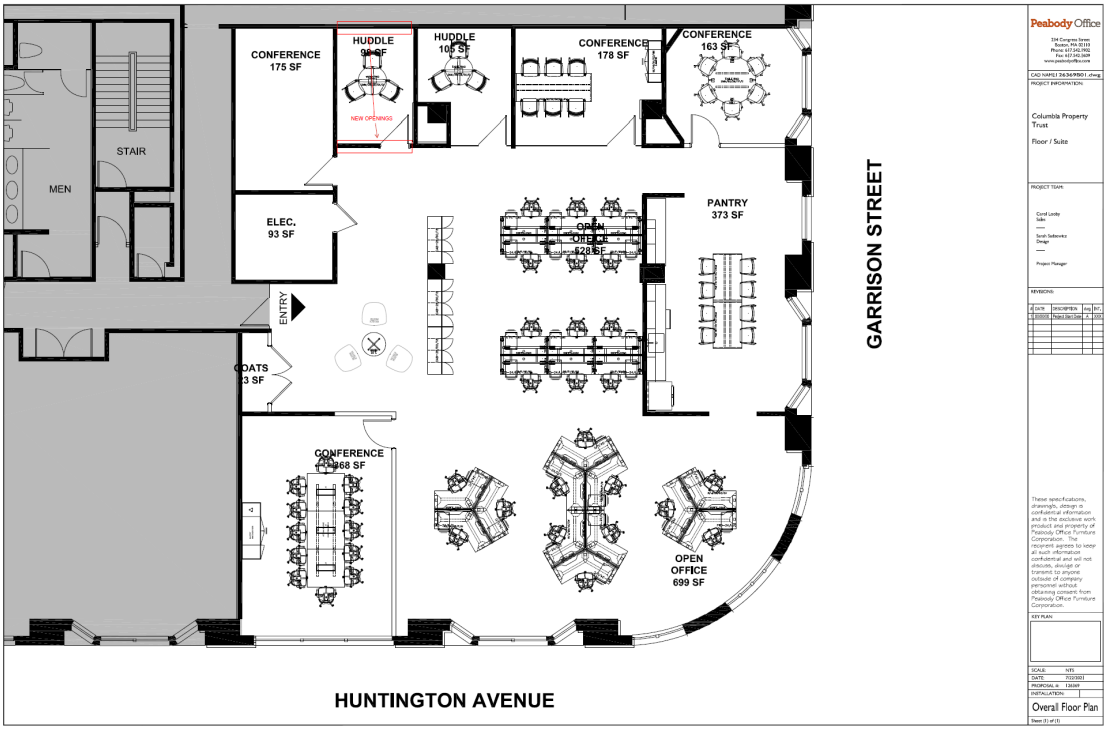

EXHIBIT B WORK AGREEMENT

1. Landlord's Work. Landlord, through its designated contractor, shall, combine the Existing Premises and the Expansion Space by creating an opening between such spaces in the area identified on Exhibit A as "New Openings" and otherwise in accordance with Landlord's plans and specifications therefor and using Landlord's Building standard practices, materials, items, and finishes ("***Landlord's Work***"). Tenant hereby acknowledges and agrees that the performance of Landlord's Work shall occur during the Move In Period and that the same shall not give rise to a claim by Tenant for any damages, set off or abatement of rent on account thereof. The parties shall use their commercially reasonable efforts to cooperate with one another in connection with the performance of Landlord's Work (including, without limitation, the scheduling, staging and moving of any of Tenant's furniture, furnishings and equipment necessary for Landlord's designated contractor to perform Landlord's Work (which moving of furniture, furnishings and equipment shall be Tenant's responsibility to do at Tenant's cost) and providing access to and from the Expansion Space by contractors, subcontractors, deliverymen and agents). Without limiting the generality of Paragraph, Tenant hereby grants Landlord, its agents, employees and contractors access to the Expansion Space at any time and from time to time to perform Landlord's Work specified above.

2. Possession. Landlord's Work shall be deemed substantially complete as reasonably determined by Landlord or Landlord's architect in its professional judgment and notwithstanding items of work and that can be completed after the Expansion Space is occupied without causing substantial interference with Tenant's use of the Expansion Space. With respect to any defect or incomplete work that is described in a written notice given by Tenant to Landlord not later than the date of substantial completion of Landlord's Work, if Landlord confirms the same are in fact defects or incomplete items, then Landlord will correct and complete the same. At Landlord's request, Tenant shall accompany Landlord to prepare the punch list on or before the date of substantial completion of Landlord's Work.

EXHIBIT C FF&E

Item	Quantity	Description
Main Area		
Grey two-seater sofa	1	
Coffee table - round, large	1	
Coffee table - round, small	1	
Box of carpet tiles	2	
Black rolling chairs	19	
Two-drawer filing cabinets	20	White metal with grey top
Desktop monitors	4	HP, LG
Stone top coffee table - round	1	
Credenza	1	
Printer	1	Brother
iPad Minis	4	Mounted outside conference rooms; for conference reservation system
Large planters	2	
Put Patients First Room (Large Conference Room)		
Black rolling chairs	17	
Black chairs	6	
TV/Computer Monitors	2	Large, Sony, mounted
Poly webcam/speaker + tablet	1	Mounted; on table
Conference table	6	Pushed together to make 1 large table
Credenza	1	Server equipment in one side; cabinet is temperature controlled
Kitchen		
Kitchen-Aid Double Door Fridge + Drawer Freezer	1	
Microwave	1	
Dishwashers	2	Stacked
Trash cans and recycling bins	4	
Bar-height chairs	8	

Water cooler	1	
Filing cabinet	1	~5.5' tall, empty, silver
Fixture: hanging lightbulbs	10	Edison bulb style
Large kitchen table	1	
Inspired to Cure Room (Smaller Conference Room)		
Round table	1	
Black rolling chairs	6	
Large whiteboard, mounted	1	
Large planter	1	Empty
TV/Computer Monitors	1	Large, Sony, mounted
Poly webcam/speaker + tablet	1	Mounted; on table
Fixture: hanging lightbulbs	10	Edison bulb style
Be Bold Room (Smaller Conference Room)		
Conference table	1	
Black rolling chairs	6	
TV/Computer Monitors	1	Large, Sony, mounted
Whiteboard, mounted	1	
Round coffee table	1	
Poly webcam/speaker + tablet	1	Mounted; on table
Embrace Change Room (Smallest Conference Room)		
Round table, small	1	
Black rolling chairs	3	
TV/Computer Monitors	1	Large, Sony, mounted
Whiteboard, mounted	1	
Poly webcam/speaker + tablet	1	Mounted; on table
Drive to Success Room (Smallest Conference Room)		
TV/Computer Monitors	1	Large, Sony, mounted
Whiteboard, mounted	1	
Poly webcam/speaker + tablet	1	Mounted; on table
Black rolling chairs	3	
Conference table	1	

Be Respectful Room		
TV/Computer Monitors	1	Large, Sony, mounted
Whiteboard, mounted	1	
Poly webcam/speaker + tablet	1	Mounted; on table
Black rolling chairs	6	
Conference table	1	Rectangular

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Claire Mazumdar, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bicara Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Claire Mazumdar
Claire Mazumdar, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ivan Hyep, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bicara Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024 By: /s/ Ivan Hyep

Ivan Hyep
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Bicara Therapeutics Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024 By: /s/ Claire Mazumdar
Claire Mazumdar, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024 By: /s/ Ivan Hyep
Ivan Hyep
Chief Financial Officer
(Principal Financial and Accounting Officer)