Bicara Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

On track to initiate FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa in 1L R/M HNSCC

Completed upsized initial public offering, raising approximately $362 million in gross proceeds, with full exercise of the underwriters' option to purchase additional shares

Strong financial position with approximately $521 million in cash and cash equivalents expected to fund operations into the first half of 2029

BOSTON, Nov. 12, 2024 – Bicara Therapeutics Inc. (Nasdaq: BCAX), a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies for patients with solid tumors, today announced financial results for the third quarter ended September 30, 2024 and provided a business update.

"The third quarter of 2024 was momentous for Bicara, highlighted by the successful completion of our upsized initial public offering, providing us with a robust balance sheet to continue to advance the development of ficerafusp alfa, our bifunctional EGFR/TGF-β inhibitor designed to exert potent anti-tumor activity directly within the tumor microenvironment," said Claire Mazumdar, PhD, MBA, Chief Executive Officer of Bicara Therapeutics. "We are currently on track to achieve several anticipated milestones, most notably the upcoming initiation of FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa, for the treatment of recurrent/metastatic head and neck squamous cell carcinoma, following encouraging interim Phase 1/1b data and alignment with the FDA on the registrational trial design. Bolstered by our strong financial position with cash runway expected to fund operations into the first half of 2029, we are committed to bringing ficerafusp alfa to patients with head and neck squamous cell carcinoma and other solid tumors as quickly as possible."

Pipeline Highlights

Bicara is developing ficerafusp alfa, a first-in-class, dual-action bifunctional epidermal growth factor receptor (EGFR)/transforming growth factor beta (TGF-β) antibody for multiple different solid tumor cancer types.

Planned Pivotal Phase 2/3 Clinical Trial in 1L R/M HNSCC

- The Company has aligned with the U.S. Food and Drug Administration on the design of FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa in combination with pembrolizumab in 1L (first line) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) and expects to initiate the trial late in the fourth quarter of 2024 or early in the first quarter of 2025.

Ongoing Phase 1/1b Clinical Trial in 1L R/M HNSCC

- In an ongoing Phase 1/1b trial, ficerafusp alfa in combination with pembrolizumab has demonstrated clinically meaningful anti-tumor activity, with a 64% overall response rate, 18%

complete response rate and median progression free survival of 9.8 months in frontline human papillomavirus (HPV)-negative R/M HNSCC, along with a favorable tolerability profile, as of the April 2024 data cut-off date (presented at the 3rd Hawaii Global Summit on Thoracic Malignancies in June 2024).
- Updated data from an ongoing Phase 1/1b trial is expected at a medical meeting in the first half of 2025.

Expansion into Other HNSCC Populations and Solid Tumor Types

- Data from a Phase 1b expansion cohort evaluating ficerafusp alfa in combination with pembrolizumab in second line (2L) or later squamous cancer of the anal canal is expected at a medical meeting in the first quarter of 2025.
- Updated data from a Phase 1b expansion cohort evaluating ficerafusp alfa monotherapy in 2L or later cutaneous squamous cell carcinoma is expected at a medical meeting in the first half of 2025.

Business Highlights

- In September 2024, Bicara completed its initial public offering (IPO) of 20,125,000 shares of its common stock at a public offering price of $18.00 per share, including full exercise of the underwriters' option to purchase additional shares, raising gross proceeds of approximately $362 million, before deducting underwriting discounts, commissions and other offering expenses. Shares began trading on the Nasdaq Global Market under the symbol "BCAX."
- In conjunction with its IPO in September 2024, Bicara appointed its President and Chief Operating Officer, Ryan Cohlhepp, PharmD, as a Director to its Board of Directors.
- In August 2024, Bicara expanded its Board of Directors with the appointments of biopharma industry leaders Mike Powell, PhD, as Chairman of the Board, and Christopher Bowden, MD, as a Director.

Third Quarter 2024 Financial Results

- **Cash Position:** As of September 30, 2024, Bicara had cash and cash equivalents of $520.8 million, compared to $230.4 million as of December 31, 2023. Based on its current operating and development plans, the Company expects that its existing cash and cash equivalents will fund operations into the first half of 2029.
- **Research and Development Expenses:** Research and development expenses were $15.9 million for the third quarter of 2024, compared to $6.9 million for the third quarter of 2023. The increase was primarily due to additional costs associated with the Company's ongoing clinical trials to advance ficerafusp alfa.
- **General and Administrative Expenses:** General and administrative expenses were $4.8 million for the third quarter of 2024, compared to $2.6 million for the third quarter of 2023. The increase in general and administrative expenses was primarily due to additional personnel costs and professional fees to prepare Bicara to operate as a public company.
- **Net Loss:** Net loss was $17.5 million for the third quarter of 2024, compared to $22.8 million for the third quarter of 2023. Net loss for the third quarter of 2023 included a $13.3 million non-

cash expense that represents the change in fair value of Bicara's Series B preferred stock tranche rights liability.

About Bicara Therapeutics

Bicara Therapeutics is a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Bicara's lead program, ficerafusp alfa, is a bifunctional antibody that combines two clinically validated targets, an epidermal growth factor receptor (EGFR) directed monoclonal antibody with a domain that binds to human transforming growth factor beta (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. Ficerafusp alfa is being developed in head and neck squamous cell carcinoma, where there remains a significant unmet need, as well as other solid tumor types. For more information, please visit www.bicara.com or follow us on LinkedIn or X.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, Bicara's expectations regarding plans for its current and future clinical trials, the anticipated timing of the initiation of FORTIFI-HN01, Bicara's pivotal Phase 2/3 clinical study, the anticipated timing of dosing patients and receiving data from Bicara's Phase 1/1b expansion cohorts evaluating ficerafusp alfa in combination with pembrolizumab; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy and tolerability, and the timing and success of interactions with and approval of regulatory authority; the anticipated contribution of the members of Bicara's board of directors to its operations and progress; and financial projections and expectations regarding the time period in which our capital resources will be sufficient to fund our anticipated operations including our cash runway, use of capital, expenses and other financial results. The words "may," "might," "will," "could," "would," "should," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks and uncertainties that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to uncertainties inherent in the development of product candidates, including the conduct of research activities and the conduct of clinical trials; uncertainties as to the availability and timing of results and data from clinical trials; whether results from prior preclinical studies and clinical trials will be predictive of the results of subsequent preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; whether Bicara's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Bicara's filings with the Securities and Exchange Commission (SEC), including Bicara's upcoming Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and any subsequent filings Bicara makes with the SEC. In addition, any forward-looking statements represent Bicara's views only as of today and should not be

relied upon as representing its views as of any subsequent date. Bicara explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Bicara intends to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investor Relations website, in addition to following the Company's press releases, SEC filings, public conference calls, presentations, and webcasts.

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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[1]	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
[1] Expenses include the following non-cash stock-based compensation expense				
Research & Development	$1,469	$398	$3,172	$924
General and administrative	562	121	1,044	210
Total stock-based compensation expense	$2,031	$519	$4,216	$1,134

BICARA THEAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(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
Total redeemable convertible preferred stock	—	367,277
Total stockholders' equity	509,555	(148,769)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 524,173	$ 233,982