UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): March 27, 2025

Bicara Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-42271**	**85-2903745**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

116 Huntington Avenue,
Suite 703 Boston, MA 02116
(Address of principal executive offices and zip code)
(617) 468-4219
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ **Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)**
- ☐ **Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)**
- ☐ **Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**
- ☐ **Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.

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. ☐

Item 2.02 - Results of Operations and Financial Condition.

On March 27, 2025, Bicara Therapeutics, Inc (the " Company ") issued a press release announcing its financial results and business highlights for the fourth quarter of fiscal year 2024 ended December 31, 2024. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information set forth under Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 - Financial Statements and Exhibits

(d) The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release of Bicara Therapeutics, Inc. dated March 27, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 27th day of March, 2025.

Bicara Therapeutics, Inc.

By:	/s/ Claire Mazumdar
Name:	Claire Mazumdar
Title:	Chief Executive Officer

Bicara Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

Dosing commenced in FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa in 1L R/M HNSCC
Updated data from ongoing Phase 1/1b trial in 1L R/M HNSCC to be presented at 2025 ASCO Annual Meeting

Strong financial position with approximately $490 million in cash and cash equivalents expected to fund operations into the first half of 2029

BOSTON, March 27, 2025 – Bicara Therapeutics Inc. (Nasdaq: BCAX), a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors, today announced financial results for the fourth quarter and full year ended December 31, 2024 and provided a business update.

"2024 was a remarkable year for Bicara, marked by our successful transition to a public company, the advancement of our lead asset, ficerafusp alfa, and the addition of key leaders to our executive team and Board of Directors. We continue to make strong progress in 2025, with patient dosing actively underway in FORTIFI-HN01, the pivotal Phase 2/3 trial of ficerafusp alfa in recurrent/metastatic head and neck squamous cell carcinoma," said Claire Mazumdar, PhD, MBA, Chief Executive Officer of Bicara Therapeutics. "As FORTIFI-HN01 progresses, we look forward to presenting updated data from our ongoing Phase 1/1b study of ficerafusp alfa in 1L R/M HNSCC at the 2025 ASCO Annual Meeting. We also continue to evaluate the potential broad utility of ficerafusp alfa across other areas of head and neck cancer, as well as other solid tumor types."

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.

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

- In February 2025, Bicara dosed the first patients in FORTIFI-HN01, a global, randomized, double-blind, placebo-controlled, 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), excluding patients with oropharyngeal squamous cell carcinoma associated with human papillomavirus infection (HPV-positive).

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

- Updated data from an ongoing Phase 1/1b trial will be presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held from May 30-June 3, 2025 in Chicago, IL.

Ongoing Phase 1/1b Expansion Cohorts and Development of Ficerafusp Alfa Across Other HNSCC Populations and Solid Tumor Types

- In January 2025, Bicara presented data from the Phase 1/1b dose expansion cohort of ficerafusp alfa in combination with pembrolizumab in patients with second line (2L) or later squamous cancer of the anal canal (SCAC) at the 2025 ASCO Gastrointestinal Cancers Symposium, providing additional support for the complementary mechanisms of ficerafusp alfa and pembrolizumab.
- Updated data from a Phase 1b expansion cohort evaluating ficerafusp alfa monotherapy in patients with 2L or later cutaneous squamous cell carcinoma (cSCC) will be presented at the American Association for Cancer Research (AACR) Annual Meeting 2025, which will be held from April 25-30, 2025 in Chicago, IL.
- A Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic colorectal cancer (RAS / BRAF wild type) is expected to initiate in 2025.
- A Phase 1b expansion cohort evaluating ficerafusp alfa in combination with pembrolizumab in HPV-positive patients with a history of heavy smoking is expected to initiate in the first half of 2025.

Upcoming Events and Presentations

- Three abstracts related to ficerafusp alfa will be presented at the upcoming AACR Annual Meeting 2025, which will be held from April 25-30, 2025 in Chicago, IL:
    - Dose expansion results of single agent ficerafusp alfa (BCA101), a bifunctional EGFR/TGF-β inhibitor in patients with metastatic or advanced cutaneous squamous cell carcinoma (cSCC) (Abstract #: CT034).
        - This presentation will highlight data from a Phase 1/1b dose expansion cohort of ficerafusp alfa monotherapy in second line or later cSCC patients.
    - Dual blockade of EGFR and TGF-β with ficerafusp alfa has the potential to overcome resistance mechanisms in 1L R/M HNSCC in combination with Pembrolizumab (Abstract #: 3284).
        - This presentation will highlight a translational medicine biomarker dataset that provides insights into the effects of targeted inhibition of TGF-β with ficerafusp alfa.
    - Ficerafusp alfa reverses acquired resistance to the KRAS-G12C inhibitor sotorasib in KRAS-G12C-mutated lung tumors (Abstract #: 4434).
        - This presentation will highlight a preclinical dataset that provides insights into the role of inhibiting TGF-β in overcoming acquired KRAS-G12C-inhibitor drug-resistant KRAS-G12C-mutated lung cancer.
        -
- Members of the Bicara management team will participate in the Stifel 2025 Virtual Targeted Oncology Forum on Tuesday, April 8, 2025 at 2:00 p.m. ET. A live webcast of the presentation will be available on the Events and Presentations section of Bicara's website. A replay of the webcast will be archived and available following the event.

Fourth Quarter and Full Year 2024 Financial Results

- **Cash Position:** As of December 31, 2024, Bicara had cash and cash equivalents of $489.7 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 $19.9 million and $63.6 million for the fourth quarter and full year ended December 31, 2024, respectively, as compared to $10.6 million and $30.6 million for the same periods in 2023. The increase was primarily due to additional costs associated with the initiation of the FORTIFI-HN01 Phase 2/3 clinical trial, as well as the Company's ongoing Phase 1/1b clinical trial to advance ficerafusp alfa.
- **General and Administrative Expenses:** General and administrative expenses were $6.8 million and $18.8 million for the fourth quarter and full year ended December 31, 2024, respectively, as compared to $3.1 million and $9.3 million for the same periods in 2023. The increase was primarily due to additional personnel costs and professional fees to prepare Bicara to operate as a public company.
- **Net Loss:** Net loss totaled $21.0 million and $68.0 million for the fourth quarter and full year ended December 31, 2024, respectively, as compared to $12.4 million and $52.0 million for the same periods in 2023. Net loss for the year ended December 31, 2023 included a $13.4 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. These statements may be identified by words such as "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 contain identifying words. Any statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, Bicara's strategy, business plans and focus; express or implied statements regarding the clinical development of ficerafusp alfa, including the initiation, timing, progress and results of ongoing and planned clinical trials; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy and tolerability; Bicara's expected operating expenses and capital expenditure requirements, including its cash runway through the first half of 2029; and participation at upcoming conferences and the timing of data readouts. 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 Annual Report on Form 10-K for the year ended December 31, 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development - related party	$ 816	$ 2,733	$ 8,216	$ 9,244
Research and development	19,067	7,829	55,403	21,373
General and administrative	6,754	3,125	18,770	9,272
Total operating expenses[1]	26,637	13,687	82,389	39,889
Loss from operations	(26,637)	(13,687)	(82,389)	(39,889)
Other (expenses) income				
Interest income	5,866	1,301	14,581	1,314
Change in fair value of Series B preferred stock tranche rights liability	—	(49)	—	(13,405)
Total other income (expense)	5,866	1,252	14,581	(12,091)
Net loss before income taxes	(20,771)	(12,435)	(67,808)	(51,980)
Income tax expense	(186)	(5)	(187)	(5)
Net loss	$ (20,957)	$ (12,440)	$ (67,995)	$ (51,985)
Net Loss per share, basic and diluted	$ (0.39)	$ (19.71)	$ (4.05)	$ (89.61)
Weighted-average number common shares outstanding, basic and diluted	54,424,607	631,286	16,805,524	580,109

[1] Expenses include the following non-cash stock-based compensation expense

Research & Development	$ 1,040	$ 171	$ 2,084	$ 381
General and administrative	2,141	594	5,313	1,518
Total stock-based compensation expense	$ 3,181	$ 765	$ 7,397	$ 1,899

BICARA THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 489,711	$ 230,440
Prepaid expenses and other assets	12,822	633
Total current assets	502,533	231,073
Property and equipment, net	155	202
Right of use asset – operating lease	690	613
Other assets	6,618	2,094
Total assets	$ 509,996	$ 233,982
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,893	$ 2,142
Accounts payable – related party	615	1,044
Accrued expenses and other current liabilities	12,875	8,053
Accrued expenses and other current liabilities – related party	—	3,561
Operating lease liability – current portion	607	285
Total current liabilities	17,990	15,085
Operating lease liability – net of current portion	131	372
Other liabilities	—	17
Total liabilities	18,121	15,474
Total redeemable convertible preferred stock	—	367,277
Total stockholders' equity (deficit)	491,875	(148,769)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 509,996	$ 233,982

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