



Bicara Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

May 13, 2025

Updated data from ongoing Phase 1/1b trial in 1L R/M HNSCC to be presented at 2025 ASCO Annual Meeting

Enrollment ongoing in FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa in 1L R/M HNSCC

Strong financial position with approximately \$462 million in cash and cash equivalents expected to fund operations into the first half of 2029

BOSTON, May 13, 2025 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2025 and provided a business update.

"We continued to execute across our clinical programs in the first quarter, maintaining strong momentum as we advance FORTIFI-HN01, the pivotal Phase 2/3 trial of ficerafusp alfa in HPV-negative recurrent/metastatic head and neck squamous cell carcinoma," said Claire Mazumdar, PhD, MBA, Chief Executive Officer of Bicara Therapeutics. "Near term, we look forward to presenting updated data from our ongoing Phase 1/1b clinical trial in this patient population as part of an oral presentation at the 2025 ASCO Annual Meeting. We believe the data have the potential to demonstrate differentiated depth and durability of response driven by the TGF- β arm of ficerafusp alfa. Additionally, we recently presented several datasets at AACR highlighting the broad therapeutic potential of ficerafusp alfa, including translational data that support its potential to prevent resistance mechanisms and potentially prolong durability in HPV-negative patients."

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.

FORTIFI-HN01: Pivotal Phase 2/3 Clinical Trial in 1L R/M HNSCC

- Enrollment is ongoing 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 with extended follow-up from an ongoing Phase 1/1b trial will be highlighted in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held from May 30-June 3, 2025 in Chicago, IL.
- Additional Phase 1b expansion cohorts evaluating ficerafusp alfa in 1L R/M HNSCC remain ongoing:
 - A cohort evaluating 750mg of ficerafusp alfa weekly in combination with pembrolizumab in HPV-negative patients has completed enrollment.
 - A cohort evaluating 2000mg of ficerafusp alfa every other week in combination with pembrolizumab in HPV-negative patients is enrolling.
 - A cohort evaluating 1500mg weekly of ficerafusp alfa in combination with pembrolizumab in HPV-neg patients with combined positive scores of 0 is enrolling.
 - A cohort evaluating ficerafusp alfa in combination with pembrolizumab in HPV-positive patients with a history of heavy smoking is expected to initiate in 2025.

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

- At the American Association for Cancer Research (AACR) Annual Meeting 2025, Bicara presented several datasets that underscore the broad therapeutic potential of ficerafusp alfa. These presentations included:
 - Preliminary findings from a translational medicine biomarker dataset from Bicara's ongoing Phase 1/1b trial of

ficerafusp alfa in 1L R/M HNSCC demonstrated that ficerafusp alfa effectively blocked TGF- β signaling and enabled tumor penetration to modulate key mechanisms associated with drug resistance.

- o Updated data from an ongoing Phase 1b expansion cohort evaluating ficerafusp alfa monotherapy in patients with second line or later cutaneous squamous cell carcinoma (cSCC) that showed continued single agent activity with an overall response rate (ORR) of 30.4% (7/23 patients) and median progression-free survival of 7.0 months (95% CI, 2.7-8.9 months), demonstrating improvements over historical treatment in cSCC.
- o New preclinical data offered insights into how TGF- β inhibition may help overcome acquired resistance to KRAS G12C inhibitors in KRAS G12C-mutant lung cancer, an important area of unmet need for patients with these types of rat sarcoma (RAS) mutations.
- A Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic colorectal cancer (RAS/B-Rapidly Accelerated Fibrosarcoma (BRAF) wild type) is expected to initiate in 2025.

Upcoming Events and Presentations

- Details of Bicara's oral presentation at 2025 ASCO Annual Meeting, which will be held from May 30-June 3, 2025 in Chicago, IL, are as follows:
 - o Title: Ficerafusp alfa with pembrolizumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: Updated results from an expansion cohort of an open-label, multicenter, Phase 1/1b trial
 - o Abstract #: 6017
 - o Session Title: Rapid Oral Abstract Session
 - o Session Category: Rapid Oral Abstract Session
 - o Session Date and Time: 6/1/2025 12:12 - 12:18 p.m. CT
 - o Location: McCormick Place Convention Center

First Quarter 2025 Financial Results

- **Cash Position:** As of March 31, 2025, Bicara had cash and cash equivalents of \$462.1 million, compared to \$489.7 million as of December 31, 2024. 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 \$34.3 million for the first quarter of 2025 as compared to \$12.0 million for the first quarter of 2024. The increase was primarily due to additional costs associated with the initiation of FORTIFI-HN01 a pivotal Phase 2/3 clinical trial, as well as the Company's ongoing Phase 1/1b clinical trials to advance ficerafusp alfa.
- **General and Administrative Expenses:** General and administrative expenses were \$7.5 million for the first quarter of 2025 as compared to \$3.3 million for the first quarter of 2024. The increase was primarily due to additional personnel costs and professional fees to support the advancement of our clinical trials and operations as a public company.
- **Net Loss:** Net loss totaled \$36.8 million for the first quarter of 2025 as compared to \$12.5 million for the first quarter of 2024.

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 Bicara's clinical development of ficerafusp alfa in combination with pembrolizumab and presentation of updated results from an expansion cohort of an open-label, multicenter, phase 1/1b trial of ficerafusp alfa with pembrolizumab in patients with recurrent or metastatic head and neck squamous cell carcinoma, the initiation, timing, progress and results of ongoing and planned clinical trials, including the initiation of additional cohorts; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability 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 its Annual Report on Form 10-K for the year ended December 31, 2024, its upcoming Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except shares and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development - related party	\$ 6,575	\$ 3,581
Research and development	27,758	8,451
General and administrative	7,455	3,342
Total operating expenses ¹	41,788	15,374
Loss from operations	(41,788)	(15,374)
Other income		
Interest income	5,014	2,867
Total other income	5,014	2,867
Net loss before income taxes	(36,774)	(12,507)
Income tax expense	(72)	(1)
Net loss	\$ (36,846)	\$ (12,508)
Net Loss per share, basic and diluted	\$ (0.68)	\$ (18.94)
Weighted-average number common shares outstanding, basic and diluted	54,456,515	660,288

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

Research & Development	\$ 1,141	\$ 230
General and administrative	2,310	917
Total stock-based compensation expense	\$ 3,451	\$ 1,147

BICARA THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		

Cash and cash equivalents	\$ 462,065	\$ 489,711
Prepaid expenses and other assets	8,689	12,822
Total current assets	<u>470,754</u>	<u>502,533</u>
Property and equipment, net	136	155
Right of use asset – operating lease	552	690
Other assets	6,635	6,618
Total assets	<u>\$ 478,077</u>	<u>\$ 509,996</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,355	\$ 3,893
Accounts payable – related party	385	615
Accrued expenses and other current liabilities	12,283	12,875
Accrued expenses and other current liabilities – related party	3,506	—
Operating lease liability – current portion	591	607
Total current liabilities	<u>19,120</u>	<u>17,990</u>
Operating lease liability – net of current portion	—	131
Total liabilities	<u>19,120</u>	<u>18,121</u>
Total stockholders' equity	<u>458,957</u>	<u>491,875</u>
Total liabilities and stockholders' equity	<u>\$ 478,077</u>	<u>\$ 509,996</u>

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