



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

Nov 10, 2025

Granted FDA Breakthrough Therapy Designation for ficerafusp alfa in combination with pembrolizumab in 1L HPV-negative R/M HNSCC

Data from a Phase 1b expansion cohort evaluating 750mg of ficerafusp alfa weekly in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients expected at ESMO Asia 2025

Strong financial position with approximately \$408 million in cash, cash equivalents, and investments as of September 30, 2025

BOSTON, Nov. 10, 2025 (GLOBE NEWSWIRE) -- Bicara Therapeutics Inc. (Nasdaq: BCAX) today announced financial results for the third quarter ended September 30, 2025 and provided a business update.

"The FDA's recent Breakthrough Therapy Designation for ficerafusp alfa in first-line HPV-negative HNSCC represents an important milestone for Bicara and validates the strength of our clinical data and our development plan, specifically underscoring the growing recognition of HPV-negative disease as a distinct clinical indication within HNSCC," said Claire Mazumdar, PhD, MBA, Chief Executive Officer of Bicara Therapeutics. "As we head into 2026, our focus continues to be on executing the enrollment of our pivotal Phase 2/3 FORTIFI-HN01 trial in first-line HPV-negative HNSCC and presenting additional data for ficerafusp alfa across dose cohorts to further characterize its tolerability and efficacy profile and inform the dose selection for our pivotal FORTIFI-HN01 study. Ficerafusp alfa is the first and only bifunctional antibody that uses an EGFR antibody backbone to localize TGF- β inhibition to increase tumor penetration and drive deep and durable responses across tumor types. We are encouraged by the evolving base of evidence that continues to demonstrate the potential of ficerafusp alfa and targeted TGF- β inhibition in HNSCC and other tumors."

Third Quarter 2025 Highlights and Recent Progress

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

- Received Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA) for ficerafusp alfa in combination with pembrolizumab for the first-line (1L) treatment of patients with metastatic or with unresectable, recurrent (R/M) head and neck squamous cell carcinoma (HNSCC) whose tumors express programmed death-ligand 1 with combined positive score (CPS) ≥ 1 , excluding human papillomavirus (HPV)-positive oropharyngeal squamous cell carcinoma.
- Continued to enroll FORTIFI-HN01, a global, randomized, double-blind, placebo-controlled, pivotal Phase 2/3 trial of ficerafusp alfa in combination with pembrolizumab 1L HPV-negative R/M HNSCC.
- Initiated a Phase 1b expansion cohort evaluating ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-positive HNSCC patients with a history of heavy smoking.

Development of Ficerafusp Alfa Across Other Solid Tumor Types

- Continued to enroll a Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic colorectal cancer (CRC) (RAS/BRAF wild type MSS).
- Presented data demonstrating the significantly improved and sustained anti-tumor effects of ficerafusp alfa compared to cetuximab in KRAS/BRAF wild-type MSS CRC cell lines, underscoring the importance of overcoming TGF- β -mediated drug resistance and facilitating immune cell tumor penetration with ficerafusp alfa, at the Society for Immunotherapy of Cancer (SITC) 2025 Annual Meeting. Access the poster presentation [here](#).
- Presented data demonstrating the ability of ficerafusp alfa to block epithelial-mesenchymal transition (EMT) and fibroblast-myofibroblast transition (FMT) in tumor cells and cancer-associated fibroblasts (CAFs), supporting ficerafusp alfa's ability to break down barriers in the tumor microenvironment (TME) and drive tumor penetration via targeted TGF- β inhibition, at the European Society for Medical Oncology (ESMO) 2025 Congress. Access the poster presentation [here](#).

Corporate Highlights

- Expanded management team with the appointments of Jenna Cohen, Chief Corporate Affairs Officer; Tanya Green, Chief Development Officer; and Bill Schelman, Senior Vice President, Clinical Development.

Key Anticipated Upcoming Milestones

- Present data from a Phase 1b expansion cohort evaluating 750mg of ficerafusp alfa weekly in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients at the ESMO Asia 2025 Meeting.
- Present data from a Phase 1b expansion cohort evaluating 2000mg of ficerafusp alfa every other week in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients in the first quarter of 2026.
- Present data from a Phase 1b expansion cohort evaluating 1500mg weekly of ficerafusp alfa in combination with pembrolizumab in HPV-negative patients with combined positive scores (CPS) of 0 in 2026.
- Present data from Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic CRC (RAS/BRAF wild type MSS) in 2026.

Third Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Investments:** As of September 30, 2025, Bicara had cash, cash equivalents and investments of \$407.6 million, compared to \$489.7 million in cash and cash equivalents as of December 31, 2024. Based on its current operating and development plans, the Company expects that its existing cash, cash equivalents and investments will fund operations into the first half of 2029.
- **Research and Development Expenses:** Research and development expenses were \$33.0 million for the third quarter of 2025 as compared to \$15.9 million for the third quarter of 2024. The increase was primarily due to costs associated with ongoing pivotal Phase 2/3 clinical trial, FORTIFI-HN01, as well as the Company's ongoing Phase 1/1b dose expansion cohorts, and an increase in personnel costs.
- **General and Administrative Expenses:** General and administrative expenses were \$7.7 million for the third quarter of 2025 as compared to \$4.8 million for the third quarter of 2024. The increase was primarily due to additional personnel costs and professional fees to support advancement of our clinical trials and operations as a public company.
- **Net Loss:** Net loss totaled \$36.3 million for the third quarter of 2025 as compared to \$17.5 million for the third quarter of 2024.

Upcoming Investor Conferences

Bicara will participate in three upcoming investor conferences:

- **Stifel Healthcare Conference 2025** on Tuesday, November 11, 2025 at 9:20 am ET.
- **Piper Sandler 37th Annual Healthcare Conference** on Tuesday, December 2, 2025 at 4:30 pm ET.
- **Evercore 8th Annual Healthcare Conference** on Wednesday, December 3, 2025 at 1:20 pm ET.

Live webcasts of the fireside chats will be accessible through the Investor Relations section of Bicara's website under [Events and Presentations](#). Replays of the webcasts will be archived and available for 30 days following each event.

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 first-in-class bifunctional antibody designed to drive tumor penetration by breaking barriers in the tumor microenvironment that have challenged the treatment of multiple solid tumor cancers. Specifically, ficerafusp alfa 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 targeted mechanism, ficerafusp alfa reverses the fibrotic and immune-excluded tumor microenvironment driven by TGF- β signaling to enable tumor penetration that drives deep and durable responses. 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](#) and [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 enrollment and progress of the FORTIFI-HN01 trial, the additional ongoing expansion cohorts of Bicara's Phase 1b trial of ficerafusp alfa and future data releases; 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 into the first half of 2029; and participation at upcoming conferences. 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 September 30, 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

(Unaudited, in thousands except shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development - related party	\$ 5,817	\$ 2,310	\$ 15,324	\$ 7,400
Research and development	27,158	13,554	76,782	36,336
General and administrative	7,701	4,764	22,376	12,016
Total operating expenses ¹	<u>40,676</u>	<u>20,628</u>	<u>114,482</u>	<u>55,752</u>
Loss from operations	(40,676)	(20,628)	(114,482)	(55,752)
Other income				
Interest income	4,386	3,147	14,082	8,715
Total other income	<u>4,386</u>	<u>3,147</u>	<u>14,082</u>	<u>8,715</u>
Net loss before income taxes	(36,290)	(17,481)	(100,400)	(47,037)
Income tax expense	(40)	-	(164)	(1)
Net loss	<u>\$ (36,330)</u>	<u>\$ (17,481)</u>	<u>\$ (100,564)</u>	<u>\$ (47,038)</u>
Net Loss per share, basic and diluted	<u>\$ (0.67)</u>	<u>\$ (1.60)</u>	<u>\$ (1.84)</u>	<u>\$ (11.27)</u>
Weighted-average number common shares outstanding, basic and diluted	<u>54,563,864</u>	<u>10,901,138</u>	<u>54,519,496</u>	<u>4,174,353</u>

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

Research & Development	\$ 1,384	\$ 562	\$ 3,684	\$ 1,044
General and administrative	2,230	1,469	6,873	3,172
Total stock-based compensation expense	<u>\$ 3,614</u>	<u>\$ 2,031</u>	<u>\$ 10,557</u>	<u>\$ 4,216</u>

BICARA THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands)

	<u>September 30, 2025</u>	<u>December 31, 2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 171,673	\$ 489,711
Prepaid expenses and other assets	7,205	12,822

Short term investments	118,494	—
Total current assets	297,372	502,533
Property and equipment, net	135	155
Right of use asset – operating lease	1,969	690
Long term investments	117,417	—
Other assets	7,795	6,618
Total assets	<u>\$ 424,688</u>	<u>\$ 509,996</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,003	\$ 3,893
Accounts payable – related party	659	615
Accrued expenses and other current liabilities	14,986	12,875
Accrued expenses and other current liabilities – related party	1,285	—
Operating lease liability – current portion	1,095	607
Total current liabilities	21,028	17,990
Operating lease liability – net of current portion	880	131
Total liabilities	21,908	18,121
Total stockholders' equity	402,780	491,875
Total liabilities and stockholders' equity	<u>\$ 424,688</u>	<u>\$ 509,996</u>

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