Bicara Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

Mar 30, 2026

Selected 1500mg weekly of ficerafusp alfa as the optimal dose and initiated Phase 3 of the FORTIFI-HN01 pivotal trial; interim analysis expected mid-2027

Announced development of a less frequent loading and every-three-week maintenance dose of ficerafusp alfa

Corporate call to discuss financial results and business updates on Monday, March 30, 2026 at 8:30 a.m. ET

BOSTON, March 30, 2026 (GLOBE NEWSWIRE) -- Bicara Therapeutics Inc. (Nasdaq: BCAX) today announced financial results for the fourth quarter and full year ended December 31, 2025 and provided a business update.

“Bicara enters the year with exceptional momentum across our clinical, regulatory, and corporate priorities,” said Claire Mazumdar, Ph.D., Chief Executive Officer at Bicara Therapeutics. “The continued advancement of our pivotal FORTIFI-HN01 study, the robust body of clinical data supporting ficerafusp alfa’s differentiated profile, and the alternate dosing option for ficerafusp alfa all underscore the significant progress we’ve made toward transforming outcomes for patients with HPV-negative head and neck cancer. Coupled with our fortified financial position from our recent financing, we are well positioned to execute on our milestones, scale our organization for potential commercialization, if approved, and deliver meaningful value for patients and shareholders throughout the year.”

Fourth Quarter 2025 Highlights and Recent Progress

FORTIFI-HN01: Pivotal Phase 2/3 Clinical Trial of Ficerafusp Alfa in First Line (1L) Recurrent or Metastatic (R/M) HPV-Negative Head and Neck Squamous Cell Carcinoma (HNSCC)

- Selected 1500mg of ficerafusp alfa as the optimal dose for the treatment of 1L HPV-negative R/M HNSCC in Phase 3 of the FORTIFI-HN01 pivotal trial.
- Initiated Phase 3 of the FORTIFI-HN01 study, and expect to be substantially enrolled by the end of the year.
- Announced plans to develop ficerafusp alfa with a loading and every-three-week (Q3W) maintenance schedule, with the goal of achieving regulatory alignment to enable data generation for potential U.S. approval.

Phase 1b Data of Ficerafusp Alfa in 1L R/M HPV-Negative HNSCC

- Presented Phase 1b data at the European Society of Medical Oncology (ESMO) Asia Congress 2025 demonstrating that ficerafusp alfa 750mg QW plus pembrolizumab was generally well-tolerated with an ORR comparable to 1500mg QW. Read the full presentation here. Biomarker analyses demonstrated that the 1500mg dose achieved greater TGF-β inhibition, stronger immune activation, and deeper clinical responses, supporting higher dose selection and further derisking the ORR interim analysis for the FORTIFI-HN01 pivotal study.
- Presented Phase 1b data at the 2026 Multidisciplinary Head and Neck Cancers Symposium (MHNCS) showing that ficerafusp alfa 2000mg Q2W plus pembrolizumab was generally well-tolerated and produced rapid, deep, and durable responses. Read the full presentation here. Updated biomarker analyses confirmed that the 2000mg Q2W regimen maintains TGF-β inhibition and immune activation consistent with the differentiated profile of 1500mg QW, supporting development of a loading and Q3W maintenance schedule that maintains efficacy and safety while providing additional convenience.

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 (mCRC) (RAS/BRAF wild type MSS).

Corporate Highlights

- Raised net proceeds of $161.8 million through an oversubscribed public offering. Net proceeds from the offering will be used to further invest in and build Bicara’s medical and commercial infrastructure to support a planned regulatory filing and commercial launch for ficerafusp alfa, if approved, in the U.S.; to further accelerate the development of ficerafusp alfa in 1L R/M HPV-negative HNSCC, including a less frequent dosing schedule; to fund manufacturing costs for ficerafusp alfa for ongoing and anticipated drug development efforts; to fund early signal-finding to support future indication expansion for

ficerafusp alfa; and for other general corporate purposes.

Key Anticipated Upcoming Milestones

HNSCC

- Present long-term follow-up data from Phase 1b study of ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-negative HNSCC at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held from May 29-June 2, 2026 in Chicago, IL.
- Achieve substantial enrollment in FORTIFI-HN01 pivotal study by the end of 2026 to enable interim analysis readout in the middle of 2027.
- Make critical commercial hires, including a Chief Commercial Officer, by the end of 2026 to advance organizational preparation for launch readiness.

Other Solid Tumors, Including mCRC

- Present data from Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ mCRC (RAS/BRAF wild type MSS) in the second half of 2026.

Fourth Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** As of December 31, 2025, Bicara had cash, cash equivalents and marketable securities of $414.8 million, compared to $489.7 million in cash and cash equivalents as of December 31, 2024. An additional $161.8 million in net proceeds was raised via an oversubscribed public offering in the first quarter of 2026. Based on its current operating and development plans, the Company expects that its existing cash, cash equivalents and marketable securities will fund operations into the first half of 2029.
- **Research and Development Expenses:** Research and development expenses were $33.0 million for the fourth quarter of 2025 as compared to $19.9 million for the fourth quarter of 2024, and $125.1 million for the full year 2025 as compared to $63.6 million for the full year 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 $8.1 million for the fourth quarter of 2025 as compared to $6.8 million for the fourth quarter of 2024, and $30.5 million for the full year 2025 as compared to $18.8 million for the full year 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 $37.4 million and $138.0 million for the fourth quarter and full year ended December 31, 2025, respectively, as compared to $21.0 million and $68.0 million for the fourth quarter and full year ended December 31, 2024, respectively.

Upcoming Investor Conferences

Bicara Therapeutics will participate in one upcoming investor conference:

- **BofA Securities Health Care Conference 2026** on Wednesday, May 13, 2026 at 9:20 a.m. PT.

A live webcast of the fireside chat will be accessible through the Investor Relations section of Bicara's website under Events and Presentations. A replay of the webcast will be archived and available for 30 days following the event.

Conference Call Information

Bicara will host a live conference call and webcast at 8:30 a.m. ET today to discuss fourth quarter and full year 2025 financial results and recent business activities. Individuals may register for the conference call by clicking the link here. Once registered, participants will receive dial-in details and a unique PIN that will allow them to access the call. An audio webcast will be accessible through the Investor Relations section of Bicara's website under Events and Presentations. An archived replay will also be available for 30 days following the event.

About Bicara Therapeutics

Bicara is a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Bicara has built a platform designed to facilitate the development of bifunctional therapies that precisely target the tumor and deliver a tumor-modulating payload to the tumor site. This approach was deployed in the development of Bicara's lead program ficerafusp alfa, formerly BCA101, a bifunctional epidermal growth factor receptor (EGFR) directed monoclonal antibody bound to a human transforming growth factor beta (TGF-β) ligand trap. By combining these two clinically validated targets, 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 (TME). Ficerafusp alfa directs the TGF-β inhibitor into the immediate TME through the binding of EGFR on tumor cells, which Bicara believes will lead to deep and durable responses and an increase in overall survival, while reducing the potential adverse effects

previously associated with systemic TGF-β inhibition. 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 anticipated substantial enrollment of the FORTIFI-HN01 pivotal trial by the end of 2026 and interim analysis readout in mid-2027, the expansion cohorts of Bicara's Phase 1/1b trial of ficerafusp alfa and the timing of future data releases; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability and tolerability; the potential for a less frequent loading and Q3W maintenance dose, including future data generation, timing of regulatory alignment, and expectations for safety, efficacy and convenience of this dosing schedule; Bicara's ability to scale and prepare for potential commercialization of ficerafusp alfa, including the planned hiring of a Chief Commercial Officer by the end of 2026; the potential for U.S. regulatory approval and launch of ficerafusp alfa; and Bicara's expected operating expenses and capital expenditure requirements, including its cash runway into the first half of 2029. 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 relating to Bicara's research and development activities; Bicara's ability to execute on its business plans and strategy, including obtaining the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to the clinical development of ficerafusp alfa; the Company's dependence on third parties; risks related to the Company's financial condition and need for additional funds in order to commercialize ficerafusp alfa, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining Bicara's intellectual property protections; and risks related to the competitive landscape for ficerafusp alfa; as well as other risks described in "Risk Factors," in Bicara's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Bicara's subsequent filings with the U.S. Securities and Exchange Commission (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 COMPREHENSIVE LOSS

(in thousands except shares and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 32,990	$ 19,883	$ 125,096	$ 63,619
General and administrative	8,132	6,754	30,508	18,770
Total operating expenses[1]	41,122	26,637	155,604	82,389
Loss from operations	(41,122)	(26,637)	(155,604)	(82,389)
Other income				
Interest income	3,789	5,866	17,871	14,581
Total other income	3,789	5,866	17,871	14,581
Net loss before income taxes	(37,333)	(20,771)	(137,733)	(67,808)
Income tax expense	(53)	(186)	(217)	(187)
Net loss	$ (37,386)	$ (20,957)	$ (137,950)	$ (67,995)
Net Loss per share, basic and diluted	$ (0.68)	$ (0.39)	$ (2.52)	$ (4.05)

Weighted-average number common shares outstanding, basic and diluted	55,142,252	54,424,607	54,676,896	16,805,524
Other comprehensive income:				
Unrealized gain on marketable securities, net of tax	379	-	243	-
Total other comprehensive income	379	-	243	-
Total comprehensive loss	$ (37,007)	$ (20,957)	$ (137,707)	$ (67,995)

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

Research & Development	$ 1,884	$ 1,040	$ 5,568	$ 2,084
General and administrative	2,565	2,141	9,438	5,313
Total stock-based compensation expense	$ 4,449	$ 3,181	$ 15,006	$ 7,397

BICARA THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 96,685	$ 489,711
Prepaid expenses and other assets	7,252	12,822
Marketable securities	318,116	-
Total current assets	422,053	502,533
Property and equipment, net	330	155
Right of use asset – operating lease	1,701	690
Other assets	6,910	6,618
Total assets	$ 430,994	$ 509,996
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,515	$ 3,893
Accounts payable – related party	2,278	615
Accrued expenses and other current liabilities	18,898	12,875
Accrued expenses and other current liabilities – related party	1,141	-
Operating lease liability – current portion	1,117	607
Total current liabilities	28,949	17,990
Operating lease liability – net of current portion	593	131
Total liabilities	29,542	18,121
Total stockholders' equity	401,452	491,875
Total liabilities and stockholders' equity	$ 430,994	$ 509,996

Contacts

Investors
Rachel Frank
IR@bicara.com

Media
Amanda Lazaro
1AB
Amanda@1abmedia.com