Bicara Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Update

Nov 9, 2026

Achieved substantial enrollment in FORTIFI-HN01 pivotal trial in 1L R/M HPV-negative HNSCC; topline results from interim analysis expected in mid-2027

Enrolling FORTIFI-FLEX alternate dosing study; expect to have data by the time of potential U.S. approval in 1L R/M HPV-negative HNSCC

Company to host conference call and webcast today, November 9, 2026 at 8:30 a.m. ET

BOSTON, Nov. 09, 2026 (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 third quarter ended September 30, 2026 and provided a business update.

“Ficerafusp alfa was purpose-built for HPV-negative head and neck cancer by inhibiting both EGFR and TGF-β, and the depth and durability of response it has demonstrated to date continue to set it apart in a disease with significant unmet need,” said Ryan Cohlhepp, President, Interim Chief Executive Officer and Chief Operating Officer of Bicara Therapeutics. “Achieving substantial enrollment in the FORTIFI-HN01 pivotal trial reflects strong execution by our team and growing recognition among investigators that HPV-negative disease requires a targeted approach grounded in its distinct biology. As we advance toward our planned interim analysis, our focus is twofold: moving with speed and aiming for ficerafusp alfa to enter the market with a competitive profile that gives physicians, patients, and payers a clear reason to choose it. At the same time, we are evaluating less-frequent dosing through FORTIFI-FLEX, which has the potential to further enhance ficerafusp alfa’s profile. With our commercial leadership team now in place, we are well-positioned as we continue to prepare to bring ficerafusp alfa to patients.”

Third Quarter 2026 Highlights and Recent Progress

Ficerafusp Alfa in 1L R/M HPV-Negative HNSCC

- Achieved substantial enrollment in the FORTIFI-HN01 pivotal trial in first-line (1L) recurrent or metastatic (R/M) human papillomavirus (HPV)-negative head and neck squamous cell carcinoma (HNSCC), to enable topline results from an interim analysis in mid-2027.
- Continue to enroll FORTIFI-FLEX, a randomized, open-label clinical trial that is evaluating ficerafusp alfa, administered as a 12-week loading dose of 1500mg weekly (QW) followed by maintenance dosing of 2250mg every three weeks (Q3W) as compared to 1500mg QW of ficerafusp alfa, each in combination with pembrolizumab. The company expects to have results from this study by the time of a potential U.S. approval in 1L R/M HPV-negative HNSCC.

Key Anticipated Upcoming Milestones

HNSCC

- Expect topline results from an interim analysis of the FORTIFI-HN01 pivotal trial in 1L R/M HPV-negative HNSCC in mid-2027.

Other Solid Tumors and Translational Data

- 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 January 2027.
- Present preclinical data evaluating the effect of tumor-targeted TGF-β neutralization with ficerafusp alfa on fibrosis and drug penetration at the European Society for Medical Oncology (ESMO) Immuno-Oncology & Advanced Therapies Congress 2026, taking place December 14-16 in London, United Kingdom.

Third Quarter 2026 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** As of September 30, 2026, Bicara had cash, cash equivalents and marketable securities of $442.3 million, compared to $414.8 million in cash, cash equivalents and marketable securities as of December 31, 2025. 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 $56.5 million for the third quarter of

2026 as compared to $33.0 million for the third quarter of 2025. The increase was primarily due to costs associated with the ongoing FORTIFI-HN01 pivotal trial, FORTIFI-FLEX trial, Phase 1/1b dose expansion cohorts, and an increase in personnel costs.

- **General and Administrative Expenses:** General and administrative expenses were $19.2 million for the third quarter of 2026 as compared to $7.7 million for the third quarter of 2025. The increase was primarily due to additional personnel costs and professional fees associated with expanding the organization as the company advances its pivotal trial and prepares for potential commercialization.
- **Net Loss:** Net loss totaled $71.2 million for the third quarter of 2026 compared to $36.3 million for the third quarter of 2025.

Upcoming Investor Conferences

Bicara will participate in the following upcoming investor conferences:

- Stifel Healthcare Conference 2026 on November 11 at 9:20 a.m. ET
- Jefferies Global Healthcare Conference on November 16 at 12:00 p.m. GMT
- Piper Sandler 38th Annual Healthcare Conference on December 2 at 8:30 a.m. 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.

Conference Call Information
Bicara will host a live conference call and webcast at 8:30 a.m. ET today to discuss third quarter 2026 financial results and business updates. 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, 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, express or implied statements regarding Bicara's strategy, business plans and focus, including the clinical development of ficerafusp alfa, including the FORTIFI-HN01 pivotal trial interim analysis readout in mid-2027, the FORTIFI-FLEX study to evaluate a loading and Q3W maintenance regimen with anticipated results by the time of a potential U.S. approval in 1L R/M HPV-negative HNSCC, and the expansion cohorts of Bicara's Phase 1/1b trial of ficerafusp alfa and the timing of future data releases; the growing recognition among investigators of the distinct biology of HPV-negative HNSCC; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability and tolerability; Bicara's ability to scale and prepare for potential commercialization of ficerafusp alfa; the potential for U.S. regulatory approval and launch of ficerafusp alfa, including our aim for ficerafusp alfa to enter the market with a competitive profile; 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, in thousands except shares and per share data)

	Three Months Ended September 30,		Nine Months EndedSeptember 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 56,476	$ 32,975	$ 149,713	$ 92,106
General and administrative	19,235	7,701	46,190	22,376
Total operating expenses[1]	75,711	40,676	195,903	114,482
Loss from operations	(75,711)	(40,676)	(195,903)	(114,482)
Other income				
Interest income	4,516	4,386	13,175	14,082
Total other income	4,516	4,386	13,175	14,082
Net loss before income taxes	(71,195)	(36,290)	(182,728)	(100,400)
Income tax expense	(54)	(40)	(168)	(164)
Net loss	$ (71,249)	$ (36,330)	$ (182,896)	$ (100,564)
Net Loss per share, basic and diluted	$ (1.04)	$ (0.67)	$ (2.78)	$ (1.84)
Weighted-average number common shares outstanding, basic and diluted	68,375,411	54,563,864	65,717,625	54,519,496
Other comprehensive loss				
Unrealized loss on marketable securities, net of tax	(1,301)	(136)	(2,112)	(136)
Total other comprehensive loss	(1,301)	(136)	(2,112)	(136)
Total comprehensive loss	$ (72,550)	$ (36,466)	$ (185,008)	$ (100,700)
[1]Expenses include the following non-cash stock-based compensation expense				
Research & Development	$ 2,911	$ 1,384	$ 9,362	$ 3,684
General and administrative	7,069	2,230	14,714	6,873
Total stock-based compensation expense	$ 9,980	$ 3,614	$ 24,076	$ 10,557

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

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 82,021	$ 96,685
Prepaid expenses and other assets	9,064	7,252

Marketable securities	360,325	318,116
Total current assets	451,410	422,053
Property and equipment, net	965	330
Right of use asset – operating lease	723	1,701
Other assets	7,544	6,910
Total assets	$ 460,642	$ 430,994
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,979	$ 5,515
Accounts payable – related party	658	2,278
Accrued expenses and other current liabilities	46,184	18,898
Accrued expenses and other current liabilities – related party	530	1,141
Operating lease liability – current portion	880	1,117
Total current liabilities	51,231	28,949
Operating lease liability – net of current portion	–	593
Total liabilities	51,231	29,542
Total stockholders' equity	409,411	401,452
Total liabilities and stockholders' equity	$ 460,642	$ 430,994

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