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

May 11, 2026

Study to evaluate ficerafusp alfa in combination with pembrolizumab as a loading and every-three-week maintenance regimen in 1L R/M HPV-negative HNSCC expected to initiate in Q3 2026

Long-term follow-up data from Phase 1b study of ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-negative HNSCC patients to be presented at ASCO 2026

Bill Schelman, M.D., Ph.D., EVP, Clinical Development promoted to Chief Medical Officer, and David Raben, M.D., Chief Medical Officer transitioned to serve as a Senior Executive Advisor to the company

Chris Sarchi appointed as Chief Commercial Officer

BOSTON, May 11, 2026 (GLOBE NEWSWIRE) -- Bicara Therapeutics Inc. (Nasdaq: BCAX) today announced financial results for the first quarter ended March 31, 2026 and provided a business update.

“The first quarter of 2026 reflects strong progress as we work to position ficerafusp alfa as the cornerstone of treatment in HPV-negative head and neck cancer. In addition to advancing our FORTIFI-HN01 pivotal trial, we continued to enroll patients in additional Phase 1b signal-seeking studies as we aim to unlock the full blockbuster potential of ficerafusp alfa. Based on recent FDA discussions, we plan to initiate a randomized study to evaluate a loading and every-three-week maintenance dosing regimen – further differentiating ficerafusp alfa and expanding optionality for patients and providers. We also look forward to sharing an important data update at ASCO 2026, which will further characterize the role of TGF-β in driving depth and durability of response across three 1L R/M HNSCC expansion cohorts,” said Claire Mazumdar, Ph.D., Chief Executive Officer at Bicara Therapeutics. “Alongside our clinical progress, we are rapidly evolving toward becoming a commercial-stage company, and to support that evolution, today we announced several executive changes. David Raben has transitioned from Chief Medical Officer to a Senior Executive Advisor role after three years of instrumental contributions, and Bill Schelman, formerly Executive Vice President of Clinical Development, has stepped into the Chief Medical Officer role. We have also welcomed Chris Sarchi as our Chief Commercial Officer, who brings extensive oncology commercialization and leadership experience as we build toward launch.”

First Quarter 2026 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)

- Continued strong execution in FORTIFI-HN01, our pivotal trial in 1L HPV-negative R/M HNSCC; expect to be substantially enrolled by the end of the year to enable an interim analysis in mid-2027 to support potential accelerated approval.
- Based on recent discussions with the U.S. Food and Drug Administration (FDA), the company plans to initiate a randomized clinical study that will evaluate ficerafusp alfa in combination with pembrolizumab, administered as a 12-week loading dose of 1500mg weekly (QW) followed by maintenance dosing of 2250mg every three weeks (Q3W). The company expects to initiate the study in the third quarter of 2026 to have results in time for potential U.S. accelerated approval.

Phase 1b Studies of Ficerafusp Alfa Across HNSCC and Other Solid Tumor Types

- Continued to enroll multiple Phase 1b expansion cohorts to identify early proof-of-concept signals and inform ficerafusp alfa development strategy beyond 1L R/M HPV-negative HNSCC.
- Published a manuscript detailing results from a Phase 1b expansion cohort evaluating 1500mg of ficerafusp alfa QW in combination with pembrolizumab in 1L R/M HNSCC in the *Journal of Clinical Oncology.* Read the manuscript here.

Corporate Highlights

- Announced that effective May 8, 2026, Bill Schelman, M.D., Ph.D., previously the company’s Executive Vice President, Clinical Development, has succeeded David Raben, M.D., as Chief Medical Officer, and Dr. Raben has transitioned to serve as a Senior Executive Advisor. With this promotion, Dr. Schelman is responsible for medical affairs and clinical development. In his new role, Dr. Raben will advise on clinical development strategy across the company’s portfolio.
- Announced that effective May 8, 2026, Chris Sarchi was appointed as Chief Commercial Officer. In this role, he will lead the commercial organization in preparation for launch readiness.

Key Anticipated Upcoming Milestones

HNSCC

- Present long-term follow-up data, which will further characterizing the role of TGF-β inhibition in driving depth and durability of response, from three Phase 1b expansion cohorts 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.

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.

First Quarter 2026 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** As of March 31, 2026, Bicara had cash, cash equivalents and marketable securities of $539.8 million, compared to $414.8 million in cash, cash equivalents and marketable securities as of December 31, 2025. The company received approximately $161.8 million in net proceeds from 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 $47.5 million for the first quarter of 2026 as compared to $34.3 million for the first quarter of 2025. The increase was primarily due to costs associated with the ongoing FORTIFI-HN01 pivotal trial, 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 $12.7 million for the first quarter of 2026 as compared to $7.5 million for the first quarter of 2025. The increase was primarily due to additional personnel costs and professional fees to support advancement of our clinical trials.
- **Net Loss:** Net loss totaled $56.2 million for the first quarter of 2026 compared to $36.8 million for the first quarter of 2025.

Upcoming Investor Conferences

Bicara Therapeutics will participate in two upcoming investor conferences:

- **BofA Securities Health Care Conference 2026** on Wednesday, May 13, 2026 at 9:20 a.m. PT.
- **TD Cowen 7th Annual Oncology Innovation Summit: Insights for ASCO & EHA** on Wednesday, May 27, 2026 at 10:30 a.m. ET.

A live webcast of the fireside chats 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 first quarter 2026 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, express or implied statements regarding Bicara’s strategy, business plans and focus; the clinical development of ficerafusp alfa, including the initiation, timing, progress, results and future data releases of Bicara’s ongoing and planned clinical trials; the advancement of the FORTIFI-HN01 pivotal trial in 1L HPV-negative R/M HNSCC and Bicara’s expectation for the trial to be substantially enrolled by the end of the year and an interim analysis mid-2027; the timing of future data releases from Bicara’s ongoing Phase 1/1b expansion cohorts; the initiation of an alternate dose study in the third quarter of 2026 to evaluate a loading and every-three-week maintenance dosing regimen of ficerafusp alfa and expectations for results in time for potential U.S. accelerated approval; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability and tolerability as compared to the existing standard of care; Bicara’s ability to scale and prepare for potential commercialization of ficerafusp alfa; anticipated contributions of members of Bicara’s leadership team; the potential for regulatory approval and U.S. 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.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Three Months Ended March 31,	
	2026	**2025**
Operating expenses		
Research and development	$ 47,500	$ 34,333
General and administrative	12,742	7,455
Total operating expenses[1]	60,242	41,788
Loss from operations	(60,242)	(41,788)
Other income		
Interest income	4,083	5,014
Total other income	4,083	5,014
Net loss before income taxes	(56,159)	(36,774)
Income tax expense	(52)	(72)
Net loss	$ (56,211)	$ (36,846)
Net Loss per share, basic and diluted	$ (0.93)	$ (0.68)
Weighted-average number common shares outstanding, basic and diluted	60,717,041	54,456,515
Other comprehensive loss:		
Unrealized loss on marketable securities, net of tax	(486)	—

Total other comprehensive loss	(486)	—
Total comprehensive loss	$ (56,697)	$ (36,846)

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

Research & Development	$ 2,225	$ 1,141
General and administrative	3,633	2,310
Total stock-based compensation expense.	$ 5,858	$ 3,451

BICARA THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 323,462	$ 96,685
Prepaid expenses and other assets	5,162	7,252
Marketable securities	216,291	318,116
Total current assets	544,915	422,053
Property and equipment, net	346	330
Right of use asset – operating lease	1,428	1,701
Other assets	6,910	6,910
Total assets	$ 553,599	$ 430,994
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,188	$ 5,515
Accounts payable – related party	1,252	2,278
Accrued expenses and other current liabilities	29,948	18,898
Accrued expenses and other current liabilities – related party	812	1,141
Operating lease liability – current portion	1,140	1,117
Total current liabilities	39,340	28,949
Operating lease liability – net of current portion	301	593
Total liabilities	39,641	29,542
Total stockholders' equity	513,958	401,452
Total liabilities and stockholders' equity	$ 553,599	$ 430,994

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