Bicara Therapeutics Reports Second Quarter 2026 Progress and Announces Strategic Leadership Transitions Marking Next Era of Execution and Growth

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President & Chief Operating Officer Ryan Cohlhepp, Pharm.D. appointed President & Chief Executive Officer effective January 2027

Claire Mazumdar, Ph.D., MBA to transition to Vice Chair of the Board of Directors and serve as Strategic Advisor

On track for substantial enrollment of pivotal FORTIFI-HN01 study by year-end, enabling topline results from interim analysis in mid-2027; initiated FORTIFI-FLEX alternate dosing study

Company to host conference call and webcast today, Tuesday, August 11, 2026 at 8:30 am ET

BOSTON, Aug. 11, 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 second quarter ended June 30, 2026 and provided a business update, including strategic leadership transitions marking the company's next era of execution and growth.

- Ryan Cohlhepp, Pharm.D., Bicara's President and Chief Operating Officer (COO) will succeed Claire Mazumdar, Ph.D., MBA as Chief Executive Officer (CEO) effective January 1, 2027. As part of this planned evolution in leadership, Dr. Mazumdar will serve as Vice Chair of the Board of Directors and Strategic Advisor, with the goal of ensuring a seamless transition as Bicara enters its next era of execution and growth. Dr. Mazumdar will leverage her deep institutional knowledge to provide management guidance and support future growth, while empowering the next phase of strategic and operational leadership at Dr. Cohlhepp's direction as the company prepares for the potential commercialization of ficerafusp alfa in first-line (1L) recurrent or metastatic (R/M) human papillomavirus (HPV)-negative head and neck squamous cell carcinoma (HNSCC), with topline data from an interim analysis of the FORTIFI-HN01 pivotal trial expected in mid-2027.
- Tanya Green, Chief Development Officer, will succeed Dr. Cohlhepp as COO, effective January 1, 2027. Since joining Bicara in October 2025, Ms. Green has demonstrated enterprise-wide responsibility for driving operational strategy, execution, and organizational performance across key development and operational functions including global clinical operations, technical operations, regulatory affairs, quality, and program management.
- Jenn Larson, CPA, has been appointed Chief Financial Officer and will succeed Ivan Hyep, MBA, effective August 12, 2026. Ms. Larson is a tenured financial operator who brings decades of experience in roles of increasing strategic and operational responsibility at publicly traded, revenue-generating, commercial-stage biotechnology organizations.
- Jenna Cohen will be promoted from Chief Corporate Affairs Officer to Chief Business Officer, effective January 1, 2027. Ms. Cohen has demonstrated an increasing scope of strategic and executional impact since joining Bicara in October 2025, and in her new role will retain oversight of corporate affairs, corporate development, and strategy.
- Greg Shiferman, J.D., has been appointed Chief Legal Officer effective August 31, 2026. Mr. Shiferman is an accomplished life sciences professional who has served in executive positions across legal and program leadership. Mr. Shiferman brings deep experience providing strategic counsel across corporate development, commercialization, and governance. He will lead all aspects of our legal and compliance functions through key corporate milestones, including the potential commercial launch of ficerafusp alfa.

"This transition marks a natural evolution for Bicara as we maintain strong enrollment momentum that enables a clear line of sight to a topline interim analysis which we believe will lead to an accelerated approval and subsequent launch of ficerafusp alfa in head and neck cancer. I am incredibly proud of what our team has accomplished so far—transforming bold science into meaningful impact for patients while establishing a strong foundation for future growth. Having worked closely with Ryan since Bicara's earliest days, I have seen firsthand his ability to translate strategy into disciplined execution, and we have been true partners in shaping the Bicara of today. I have complete confidence that he is the right leader to guide our next chapter," said Claire Mazumdar, Ph.D., MBA, Chief Executive Officer of Bicara Therapeutics. "In addition, I want to thank Ivan for serving as an early executive at Bicara, for leading us through private and public offerings during his tenure, and for establishing the early infrastructure for the Finance organization. In my new role, I look forward to continuing to help shape the future of Bicara—both on the Board and supporting the leadership team as they build on this momentum and continue creating lasting value for patients, employees, and shareholders."

"On behalf of the Board, I want to thank Claire for her extraordinary vision, leadership, and commitment to building a company defined by scientific excellence, a deeply rooted culture, and an unwavering focus on patients. Throughout her tenure, Claire has led with a long-term perspective, and this leadership transition reflects her thoughtful stewardship and commitment to Bicara's

continued success," said Mike Powell, Chairman of the Board of Bicara Therapeutics. "The Board has great confidence in Ryan to lead Bicara into its next era of execution and growth. This transition also reflects the investments we have made to prepare for our next chapter—including strengthening our executive team with experienced commercial leaders, elevating outstanding internal talent, and expanding the Board with directors who bring deep operational and commercialization expertise. Together, these steps have created a management team equipped to execute on the significant opportunities ahead, position the company for its next stage of growth, and broaden Bicara's impact for patients."

"It is an incredible privilege to lead Bicara at such an important moment in its journey. Since the early days of Bicara, I have had the opportunity to help shape our strategy, help build the organizational capabilities and leadership team at the appropriate time in the company's evolution, and work alongside an extraordinary group of colleagues to bring the tremendous promise of ficerafusp alfa to many people around the world through our clinical trials," said Ryan Cohlhepp, President and COO. "I am deeply grateful to Claire for her partnership and unwavering commitment to the ongoing success of this organization, and to the Board for its confidence in me. As we look ahead, my focus will be on building on the exceptional foundation we have created together —establishing our commercial footprint, advancing a pipeline with discipline and purpose, and continuing to invest in the people and culture that make Bicara unique."

Leadership biographies may be accessed on the Bicara website.

Second Quarter 2026 Highlights and Recent Progress

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

- Initiated FORTIFI-FLEX, a randomized, open-label, 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 have results from this study by the time of a potential U.S. accelerated approval in 1L R/M HPV-negative HNSCC.
- Presented extended follow-up data out to three years from the Phase 1/1b 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. The data demonstrated deep, durable responses representing substantial improvements over standard of care treatment, observed to be driven by TGF-β inhibition, allowing for direct tumor penetration. Specifically, three-year follow-up from the 1500mg QW dose cohort showed an estimated OS rate of 31%, approximately doubling the survival rate observed in retrospective analysis with standard of care pembrolizumab in HPV-negative patients.

Key Anticipated Upcoming Milestones

HNSCC

- Continued to enroll Phase 3 of the FORTIFI-HN01 pivotal trial in 1L R/M HPV-negative HNSCC and expect to be substantially enrolled by the end of the year to enable topline results from an interim analysis in mid-2027.

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.

Second Quarter 2026 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** As of June 30, 2026, Bicara had cash, cash equivalents and marketable securities of $497.3 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 $45.8 million for the second quarter of 2026 as compared to $24.8 million for the second 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 $14.2 million for the second quarter of 2026 as compared to $7.2 million for the second quarter of 2025. The increase was primarily due to additional personnel costs and professional fees associated with expanding the organization as we advance in a pivotal study and prepare for potential commercialization.
- **Net Loss:** Net loss totaled $55.4 million for the second quarter of 2026 compared to $27.4 million for the second quarter of 2025.

Upcoming Investor Conference

Bicara Therapeutics will participate in one upcoming investor conference:

- 2026 Cantor Global Healthcare Conference on Wednesday, September 9, 2026 at 9:10 a.m. ET.

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 second quarter 2026 financial results and business updates, including strategic leadership transitions. 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 anticipated substantial enrollment of the FORTIFI-HN01 pivotal trial by the end of 2026 and interim analysis readout in mid-2027, the alternate dose study to evaluate a loading and Q3W maintenance regimen with anticipated results by the time of a potential U.S. accelerated 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 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; Bicara's expected operating expenses and capital expenditure requirements, including its cash runway into the first half of 2029; and anticipated contributions by members of Bicara's Board and management team. 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 June 30,		Six Months EndedJune 30,	
	2026	2025	2026	2025
Operating expenses				

Research and development	$ 45,773	$ 24,798	$ 93,237	$ 59,131
General and administrative	14,178	7,220	26,954	14,675
Total operating expenses[1]	59,951	32,018	120,191	73,806
Loss from operations	(59,951)	(32,018)	(120,191)	(73,806)
Other income				
Interest income	4,576	4,682	8,659	9,696
Total other income	4,576	4,682	8,659	9,696
Net loss before income taxes	(55,375)	(27,336)	(111,532)	(64,110)
Income tax expense	(61)	(52)	(115)	(124)
Net loss	$ (55,436)	$ (27,388)	$ (111,647)	$ (64,234)
Net Loss per share, basic and diluted	$ (0.82)	$ (0.50)	$ (1.73)	$ (1.18)
Weighted-average number common shares outstanding, basic and diluted	67,925,963	54,539,230	64,360,558	54,496,862
Other comprehensive loss				
Unrealized loss on marketable securities, net of tax	(324)	_	(810)	_
Total other comprehensive loss	(324)	_	(810)	_
Total comprehensive loss	$ (55,760)	$ (27,388)	$ (112,457)	$ (64,234)
[1]Expenses include the following non-cash stock-based compensation expense				
Research & Development	$ 4,226	$ 1,159	$ 6,451	$ 2,300
General and administrative	4,012	2,333	7,645	4,643
Total stock-based compensation expense	$ 8,238	$ 3,492	$ 14,096	$ 6,943

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

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 96,599	$ 96,685
Prepaid expenses and other assets	6,561	7,252
Marketable securities	400,660	318,116
Total current assets	503,820	422,053
Property and equipment, net	362	330
Right of use asset – operating lease	1,151	1,701
Other assets	6,910	6,910
Total assets	$ 512,243	$ 430,994
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 7,431	$ 5,515
Accounts payable – related party	1,032	2,278
Accrued expenses and other current liabilities	33,666	18,898
Accrued expenses and other current liabilities – related party	183	1,141
Operating lease liability – current portion	1,163	1,117
Total current liabilities	43,475	28,949
Operating lease liability – net of current portion	–	593
Total liabilities	43,475	29,542
Total stockholders' equity	468,768	401,452
Total liabilities and stockholders' equity	$ 512,243	$ 430,994

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