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

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Updated data from Phase 1/1b trial presented at 2025 ASCO Annual Meeting demonstrated deep and durable responses in 1L HPV-negative R/M HNSCC

Data from additional Phase 1/1b expansion cohorts evaluating alternate dose regimens in HPV-negative patients expected by Q1 2026

Strong financial position with approximately $437 million in cash and cash equivalents as of June 30, 2025 expected to fund operations into the first half of 2029

BOSTON, Aug. 12, 2025 (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, 2025 and provided a business update.

“We continue to make excellent progress with the development of ficerafusp alfa,” said Claire Mazumdar, PhD, MBA, Chief Executive Officer of Bicara Therapeutics. “Updated Phase 1/1b data recently presented at ASCO 2025 from the 1500mg weekly cohort underscore the differentiated ability of ficerafusp alfa to remodel the tumor stroma and drive tumor penetration, with deep, durable anti-tumor responses observed in HPV-negative recurrent/metastatic head and neck squamous cell carcinoma patients. These data provide a strong foundation for the continued advancement of our pivotal Phase 2/3 FORTIFI-HN01 trial, and reinforce our confidence in the study design. We also look forward to presenting data from two additional Phase 1/1b expansion cohorts evaluating alternate dose regimens in patients with HPV-negative disease, which are expected to further characterize the safety and efficacy profile of ficerafusp alfa in this population with high unmet need.”

Pipeline Highlights

Bicara is developing ficerafusp alfa, a first-in-class, dual-action bifunctional epidermal growth factor receptor (EGFR)/transforming growth factor beta (TGF-β) antibody designed to enhance tumor penetration by breaking barriers in the tumor microenvironment that have challenged the treatment of multiple solid tumor cancers.

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

Enrollment is ongoing in FORTIFI-HN01, a global, randomized, double-blind, placebo-controlled, pivotal Phase 2/3 trial of ficerafusp alfa in combination with pembrolizumab in first line (1L) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC), excluding patients with oropharyngeal squamous cell carcinoma associated with human papillomavirus infection (HPV-positive).

Phase 1/1b Clinical Trial in 1L R/M HNSCC

- Updated data with extended follow-up from a Phase 1/1b trial evaluating 1500mg ficerafusp alfa weekly in patients with 1L R/M HNSCC was highlighted in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.
  - In the efficacy evaluable human papillomavirus (HPV)-negative population (n=28):
    - Median duration of response (DOR) of 21.7 months amongst responders (n=15).
    - Median overall survival (OS) of 21.3 months; 2-year OS rate of 46%.
    - 54% (15/28) confirmed objective response rate (ORR); 64% (18/28) ORR, including three additional unconfirmed responses and 21% (6/28) complete response rate.
    - 80% (12/15) of responders achieved a deep response (≥80% tumor shrinkage).
    - Disease control rate of 89% (25/28 patients).
    - Median progression-free survival of 9.9 months.
    - Manageable safety profile consistent with previously reported adverse events.
- Additional Phase 1b expansion cohorts evaluating ficerafusp alfa in 1L R/M HNSCC remain ongoing:
  - Data from a cohort evaluating 750mg of ficerafusp alfa weekly in combination with pembrolizumab in HPV-negative

patients are expected to be presented at a medical meeting in the fourth quarter of 2025 or the first quarter of 2026.

- Data from a cohort evaluating 2000mg of ficerafusp alfa every other week in combination with pembrolizumab in HPV-negative patients are expected to be presented at a medical meeting in the first quarter of 2026.
- A cohort evaluating 1500mg weekly of ficerafusp alfa in combination with pembrolizumab in HPV-negative patients with combined positive scores (CPS) of 0 continues to enroll. Data from this cohort are expected to be presented at a medical meeting in 2026.

Development of Ficerafusp Alfa Across Other Solid Tumor Types

- A Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic colorectal cancer (RAS/B-Rapidly Accelerated Fibrosarcoma (BRAF) wild type) is enrolling.

Second Quarter 2025 Financial Results

- **Cash Position:** As of June 30, 2025, Bicara had cash and cash equivalents of $436.6 million, compared to $489.7 million as of December 31, 2024. Based on its current operating and development plans, the Company expects that its existing cash and cash equivalents will fund operations into the first half of 2029.
- **Research and Development Expenses:** Research and development expenses were $24.8 million for the second quarter of 2025 as compared to $15.8 million for the second quarter of 2024. The increase was primarily due to additional costs associated with the initiation of FORTIFI-HN01, a pivotal Phase 2/3 clinical trial, as well as the Company's ongoing Phase 1/1b clinical trials to advance ficerafusp alfa and an increase in personnel costs.
- **General and Administrative Expenses:** General and administrative expenses were $7.2 million for the second quarter of 2025 as compared to $3.9 million for the second 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 $27.4 million for the second quarter of 2025 as compared to $17.0 million for the second quarter of 2024.

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 or 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, progress and anticipated data readouts of Bicara's Phase 2/3 trial of ficerafusp alfa in combination with pembrolizumab and the additional ongoing expansion cohorts of Bicara's Phase 1b trial of ficerafusp alfa; 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 and the timing of data readouts. 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 June 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development - related party	$ 2,932	$ 1,510	$ 9,507	$ 5,091
Research and development	21,866	14,331	49,624	22,782
General and administrative	7,220	3,909	14,675	7,251
Total operating expenses[1]	32,018	19,750	73,806	35,124
Loss from operations	(32,018)	(19,750)	(73,806)	(35,124)
Other income				
Interest income	4,682	2,701	9,696	5,568
Total other income	4,682	2,701	9,696	5,568
Net loss before income taxes	(27,336)	(17,049)	(64,110)	(29,556)
Income tax expense	(52)	–	(124)	(1)
Net loss	$ (27,388)	$ (17,049)	$ (64,234)	$ (29,557)
Net Loss per share, basic and diluted	$ (0.50)	$ (19.01)	$ (1.18)	$ (38.19)
Weighted-average number common shares outstanding, basic and diluted	54,539,230	896,744	54,496,862	774,012
[1] Expenses include the following non-cash stock-based compensation expense				
Research & Development	$ 1,159	$ 251	$ 2,300	$ 481
General and administrative	2,333	787	4,643	1,704
Total stock-based compensation expense	$ 3,492	$ 1,038	$ 6,943	$ 2,185

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 436,606	$ 489,711
Prepaid expenses and other assets	7,785	12,822
Total current assets	444,391	502,533
Property and equipment, net	117	155
Right of use asset – operating lease	2,237	690
Other assets	6,842	6,618
Total assets	$ 453,587	$ 509,996
Liabilities and stockholders' equity		
Current liabilities:		

Accounts payable	$ 2,041	$ 3,893
Accounts payable – related party	870	615
Accrued expenses and other current liabilities	12,000	12,875
Accrued expenses and other current liabilities – related party	1,242	—
Operating lease liability – current portion	1,074	607
Total current liabilities	17,227	17,990
Operating lease liability – net of current portion	1,164	131
Total liabilities	18,391	18,121
Total stockholders' equity	435,196	491,875
Total liabilities and stockholders’ equity	$ 453,587	$ 509,996

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