UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): January 12, 2026

Bicara Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-42271**	**83-2903745**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

116 Huntington Avenue,
Suite 703 Boston, MA 02116
(Address of principal executive offices and zip code)
(617) 468-4219
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ **Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)**
- ☐ **Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)**
- ☐ **Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**
- ☐ **Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	BCAX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 - Other Events.

On January 12, 2026, Bicara Therapeutics Inc. issued a press release entitled "Bicara Therapeutics Announces Phase 3 Optimal Dose and Provides 2026 Corporate Outlook." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits

(d) The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release, dated January 12, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 12th day of January 12, 2026.

Bicara Therapeutics Inc.

By:	/s/ Claire Mazumdar
Name:	Claire Mazumdar, Ph.D.
Title:	Chief Executive Officer

Bicara Therapeutics Announces Phase 3 Optimal Dose and Provides 2026 Corporate Outlook

Selected 1500 mg of ficerafusp alfa as the optimal dose for the treatment of 1L HPV-negative R/M HNSCC in Phase 3 FORTIFI-HN01 pivotal study

Expects to achieve substantial enrollment in FORTIFI-HN01 in 2026 to enable interim analysis in mid-2027

Anticipates multiple expansion cohort data readouts in 2026 to further characterize ficerafusp alfa's profile in HPV-negative HNSCC and support potential expansion into other solid tumor types, including colorectal cancer

Claire Mazumdar, PhD, MBA, Chief Executive Officer, to present at the J.P. Morgan 2026 Healthcare Conference on Monday, January 12 at 11:15 a.m. PT (2:15 p.m. ET)

BOSTON, January 12, 2026 – Bicara Therapeutics Inc. (Nasdaq: BCAX), a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors, today provided a 2026 corporate outlook and strategy for continued growth, building upon the clinical success of ficerafusp alfa, the first and only bifunctional epidermal growth factor receptor (EGFR)-directed antibody combined with a TGF-β ligand trap designed to drive increased tumor penetration and improve survival outcomes.

"Bicara is entering 2026 with strong momentum and a clear plan for growth as we advance ficerafusp alfa, designed to generate significantly improved clinical outcomes in head and neck cancer that we believe will translate to commercial success," said Claire Mazumdar, PhD, MBA, Chief Executive Officer at Bicara Therapeutics. "We are thrilled to announce that we have selected 1500 mg of ficerafusp alfa as the optimal dose for Phase 3 of the FORTIFI-HN01 pivotal study. Our focus for 2026 is to accelerate enrollment and end the year with a clear line of sight to an interim analysis in mid-2027 to support a potential accelerated filing. Our goal is to ensure that we are best positioned to achieve ficerafusp alfa's blockbuster commercial potential, while advancing other signal-finding efforts that are based upon clear biologic and mechanistic rationale to better characterize ficerafusp alfa's pipeline-in-a-product potential."

Selected 1500 mg QW of ficerafusp alfa in combination with pembrolizumab as the optimal dose for Phase 3 FORTIFI-HN01 pivotal study, earlier than anticipated

Bicara has aligned with the U.S. Food and Drug Administration (FDA) on a clear path to implement, by the end of the first quarter, the optimal dose for Phase 3 of FORTIFI-HN01, a global, randomized, double-blind, placebo-controlled, pivotal trial of ficerafusp alfa in combination with pembrolizumab in first-line (1L) human papillomavirus (HPV)-negative recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).

Executing our strategic development plan for FICERA
The company anticipates that FORTIFI-HN01 will be substantially enrolled by the end of 2026 to enable an interim analysis in the middle of 2027.

Preparing for a successful commercial launch in HPV-negative HNSCC, a large and growing market with significant unmet need
Ficerafusp alfa has the potential to achieve blockbuster status in HPV-negative R/M HNSCC, a multi-billion-dollar market that continues to grow. HPV-negative R/M HNSCC is a biologically distinct disease, often marked by immune exclusion and a hostile tumor microenvironment that limits the depth and durability of response to currently available therapies. Moreover, the majority of patients rapidly develop therapeutic resistance, underscoring the urgent need for more effective and durable treatment options.

Ficerafusp alfa has a proven clinical dataset that more than doubles median overall survival in HPV-negative patients compared to standard of care and substantially improves upon median duration of response compared to other pembrolizumab combinations, including other approved and investigational EGFR-targeting agents. With increased conviction in ficerafusp alfa's clinical potential, and as the company accelerates enrollment in the FORTIFI-HN01 pivotal study, Bicara plans to make critical commercial hires in 2026 to establish a strong foundation for future commercial success.

Following EGFR and TGF-β biology to expand ficerafusp alfa's potential while maintaining financial discipline
Ficerafusp alfa is the first and only bifunctional EGFR-directed antibody combined with a TGF-β ligand trap designed to drive increased tumor penetration and improve survival outcomes. By simultaneously targeting EGFR-expressing tumor cells and modulating TGF-β–driven tumor microenvironment signaling, ficerafusp alfa is designed to improve tumor accessibility and enable more effective immune activity within the tumor. This bifunctional approach is intended to support deeper and more durable anti-tumor responses when used in combination with immune checkpoint inhibitors.

There is a compelling biological rationale to explore ficerafusp alfa's potential in solid tumors outside of HNSCC, especially in indications where EGFR is overexpressed and TGF-β signaling contributes to tumor progression. Bicara is currently evaluating ficerafusp alfa in metastatic colorectal cancer (mCRC) and plans to expand signal-finding efforts in other solid tumors with significant unmet need to further evaluate ficerafusp alfa's pipeline-in-a-product potential.

2026 Corporate Milestones

HNSCC
- Present data from an exploratory Phase 1b expansion cohort evaluating 2000 mg of ficerafusp alfa every other week in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients in the first quarter of 2026 to inform alternate dosing strategy for commercialization.
- Present long-term follow-up data from Phase 1b study of ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-negative HNSCC in the second quarter of 2026.
- Achieve substantial enrollment in FORTIFI-HN01 pivotal study by the end of 2026 to enable interim analysis 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.

J.P. Morgan Healthcare Conference Presentation Information

Claire Mazumdar, PhD, MBA, Chief Executive Officer, will present at the J.P. Morgan 2026 Healthcare Conference on Monday, January 12, at 11:15 a.m. PT (2:15 p.m. ET). A live webcast of the presentation 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 following the event.

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 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 Bicara's clinical development of ficerafusp alfa both as a monotherapy and in combination with pembrolizumab, including the anticipated data readouts in 2026 and potential expansion of ficerafusp alfa into other solid tumor types, the timing of the implementation of the optimal dose for Phase 3 of FORTIFI-HN01, the potential path with the FDA regarding such implementation and the benefits associated therewith, the planned substantial enrollment in the FORTIFI-HN01 pivotal study in 2026 and potential interim analysis in the middle of 2027, the expected therapeutic potential and clinical benefits of ficerafusp alfa and Bicara's commercialization plans. 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, preliminary or interim data from earlier stage 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 Quarterly Report on Form 10-Q for the quarter ended September 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.

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