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): August 20, 2026

ADAPTIN BIO, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-56583**	**88-1566415**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3540 Toringdon Way, Suite 200, #250 Charlotte, North Carolina	28277
(Address of Principal Executive Offices)	(Zip Code)

(888)-609-1498
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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: None.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 August 20, 2026, Adaptin Bio, Inc. announced that enrollment has opened for a Phase 1 clinical trial evaluating its proprietary BRiTE (Brain Bispecific T cell Engager) therapeutic, APTN-101, as a treatment for glioblastoma. 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) Exhibits

Exhibit No.	Description
99.1	Press release, dated August 20, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Adaptin Bio, Inc.

Date: August 25, 2026

By: */s/* Michael J. Roberts
Michael J. Roberts
President and Chief Executive Officer

Exhibit 99.1

Adaptin Bio Announces Opening of Enrollment in a Phase 1 Clinical Trial Evaluating Treatment of Malignant Brain Tumors with APTN-101

APTN-101's unique mechanism of action is designed to overcome the limitations for effective treatment of malignant brain tumors by enhancing the transport of therapies across the blood-brain barrier and selectively targeting EGFRvIII^{+} glioma cells

Phase 1 study being conducted in collaboration with Duke University

CHARLOTTE, N.C.— August 20, 2026—Adaptin Bio, Inc. (OTCQB: APTN) ("Adaptin" or the "Company"), a biotechnology company focused on developing precision cancer therapies with improved delivery to the brain and other tissues, announced today that enrollment has opened for a Phase 1 clinical trial evaluating its proprietary BRiTE (Brain Bispecific T cell Engager) therapeutic, APTN-101, as a treatment for glioblastoma (GBM), the most common and aggressive primary brain tumor. The BRiTE platform was developed by a distinguished team of researchers at Duke University, the study site for the first-in-human clinical trial.

The Phase 1 clinical trial has an open-label, dose-escalation design with the primary objective to evaluate the safety profile and maximum tolerated dose of APTN-101 in patients diagnosed with World Health Organization (WHO) Grade IV Malignant Glioma (GBM that expresses Epidermal Growth Factor Receptor variant III [EGFRvIII]). The study is expected to enroll up to 15 adult patients, and the primary endpoint is the proportion of patients with a dose limiting toxicity observed within each dose level. Secondary endpoints are the pharmacokinetics of APTN-101, and the objective response rate based on modified Response Assessment in Neuro-Oncology Criteria. Exploratory endpoints include an assessment of biological activity as evidenced by changes in cytokine levels, formation of anti-BRiTE antibodies, overall survival and progression free survival.

"Opening enrollment in the Phase 1 trial is an important milestone in the clinical development of APTN-101, a potential best-in-class therapy for the treatment of glioblastoma," said Michael J. Roberts, Ph.D., President and CEO of Adaptin Bio. "In preclinical studies, APTN-101 demonstrated impressive efficacy targeting glioma cells with precision, eliminating some malignant glioma tumors across multiple aggressive disease models. Our proprietary BRiTE technology was developed to enhance APTN-101's ability to cross the blood-brain barrier, to selectively target and then attack glioma tumor cells. We believe this mechanism of action is a significant innovation that provides a key differentiator compared to standard-of-care therapies. Since such standard-of-care therapies (including surgery, radiotherapy and chemotherapy) are not curative, disease recurrence is common. As a result, patients diagnosed with GBM currently have a median survival of only 12 to 18 months with just 5% of patients surviving beyond five years. Given the promising preclinical data that has been generated for APTN-101 so far, we believe that leveraging the BRiTE technology with APTN-101 has potential to become an important therapeutic option for patients diagnosed with this difficult-to-treat disease."

BRiTE's unique delivery mechanism and mode of action harness the ability of T cells to precisely target and destroy glioma cells while effectively navigating the brain's unique environment. Specifically, APTN-101 is engineered to cross the blood-brain barrier (BBB) to target EGFRvIII, a specific protein linked to aggressive brain tumors. In preclinical studies, APTN-101 demonstrated a greater than 7-fold increase in distribution of the EGFRvIII T-cell engager into the brain compared to the EGFRvIII T-cell engager alone. This resulted in complete eradication of EGFRvIII GMB tumors in 70%-80% of mice. The novel treatment is associated with an excellent safety profile and minimal off-target effects in preclinical models.

"Glioblastoma is a disease with a significant unmet clinical need, limited therapeutic options, and little improvement in outcomes," said Mustafa Khasraw, M.D., professor at Duke University School of Medicine, who led the preclinical development team for APTN-101 and is the principal investigator of the upcoming clinical trial. "By combining immune-based tumor targeting with enhanced delivery to the brain, APTN-101 is designed to address two major challenges in glioblastoma treatment. This first-in-human study is an important step in determining whether this approach can translate into meaningful benefit for patients."

Glioblastoma is one of the most aggressive and deadly forms of brain cancer, accounting for approximately 15,000 new cases per year in the U.S. Secondary malignant brain tumors account for about 200,000 new cases annually. The glioblastoma multiforme treatment market is valued at $3.02 billion in 2025, and researchers forecast an 8% CAGR over the next five years, reaching $4.44 billion by 2030.[1] Growing demand for therapies that prolong survival is a top driver of the projected growth.

[1] Source: https://www.mordorintelligence.com/industry-reports/glioblastoma-multiforme-treatment-market

About BRiTE

Adaptin Bio's proprietary BRiTE technology leverages the enhanced "hitchhiking" capabilities of manipulated immune cells to deliver therapeutic agents directly to brain tumors. This innovative approach has demonstrated high specificity for EGFRvIII expressing glioma cells, dose-responsive efficacy against diverse patient-derived glioma cell lines, and a favorable safety profile. Additional BRiTE targets are being evaluated. By manipulating the immune system either in vivo or ex vivo, BRiTE aims to overcome traditional treatment barriers and offer a promising new therapeutic option for patients with intracerebral malignancies.

Adaptin Bio, Inc.

Adaptin Bio, Inc. is a biotechnology company developing novel therapies for oncology and central nervous system disorders with improved drug delivery to the brain and other tissues. The company's proprietary Brain Bispecific T cell Engager (BRiTE) technology was developed by researchers at the Department of Neurosurgery at Duke University. The Company's mission is to develop novel therapies to improve patient outcomes in difficult-to-treat cancers as well as other disease states that can benefit from a precisely targeted treatment. For more information, visit www.adaptinbio.com.

Caution Regarding Forward Looking Statements:

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. These forward-looking statements may include information concerning our clinical trials and possible or projected future business operations. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: risks of our clinical trials, including, but not limited to, the timing, delays, costs, design, initiation, enrollment, and results of such trials; any delays in regulatory review and approval of product candidates in development; reliance on third parties to supply drug substance and drug product for our clinical trials and preclinical studies, and produce commercial supplies of product candidates; the potential advantages of our product candidates; our ability to market and commercialize our products, if approved; our product candidates' ability to achieve market acceptance, if approved; our competitive position; our estimates regarding the potential market opportunity for our product candidates; our ability to raise additional money to fund our operations for at least the next 12 months as a going concern and develop our product candidates as anticipated; our ability to control costs associated with our operations; risks related to our ability to develop a market for common stock; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including on our Board of Directors; intellectual property risks; volatility and uncertainty in the global economy and financial markets; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and other risks and uncertainties set forth from time to time in our SEC filings. Adaptin assumes no obligation and does not intend to update these forward-looking statements except as required by law.

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