

**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): February 12, 2026

BioXcel Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38410
(Commission File Number)

82-1386754
(I.R.S. Employer
Identification No.)

555 Long Wharf Drive
New Haven, CT 06511
(Address of principal executive offices, including Zip Code)

(475) 238-6837
(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	BTAI	The Nasdaq Capital Market

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 February 12, 2026, BioXcel Therapeutics, Inc. (the “Company”) announced the completion of an updated market opportunity assessment for IGALMI® for acute agitation associated with bipolar disorders or schizophrenia in the at-home (outpatient) setting, informed by results from the SERENITY At-Home clinical study. The Company submitted a supplemental New Drug Application (sNDA) last month seeking the FDA’s approval of IGALMI for at-home use in the acute treatment of agitation associated with bipolar disorders or schizophrenia.

The commercial opportunity assessment was based on recently completed market research leveraging an updated Target Product Profile based on results from the SERENITY At-Home clinical study. The assessment incorporated interviews with 15 prescribers and 5 payers with leadership responsibility at large health plans as well as survey responses from 180 prescribers with extensive relevant experience. In addition, patient-level claims analyses were used to estimate the number of diagnosed and treated patients who may be candidates for IGALMI.

Current agitation landscape insights from the assessment included:

- Prescribers reported a moderate to high unmet need, noting that current treatment options are not indicated for at-home use, may be sedating, are slow to take effect, and/or are controlled substances with the potential to cause dependence.
- Analyses of market research and claims data identified approximately 2.3 million treated bipolar disorder and schizophrenia patients experiencing frequent episodes of acute agitation in the at-home setting in the United States, of whom up to 1.8 million may be eligible for IGALMI treatment. This represents up to 86 million addressable annual episodes that may require treatment. This updated estimate is generally consistent with prior estimates of approximately 57-77 million addressable annual episodes, with further refinement based on the additional insights from market research.

IGALMI opportunity in the at-home setting based on the assessment included:

- Prescribers reported moderate to high interest in IGALMI for the treatment of acute agitation in the at-home setting, projecting use in approximately 70% of their schizophrenia and bipolar disorder patients, regardless of agitation severity.
 - Prescribers anticipated that IGALMI would be used either alone or in combination with existing off-label treatments for acute agitation, and that IGALMI would most frequently replace benzodiazepines, which may cause dependence.
 - Payers indicated expectations for broad formulary coverage with standard adjudication controls.
 - Previously reported patient and caregiver research (N=80) indicated that patients with schizophrenia and bipolar disorder would expect to use IGALMI in approximately 80% of their acute agitation episodes.
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Forward-Looking Statements

This Current Report on Form 8-K includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Current Report on Form 8-K other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: the approval of IGALMI for use in the at-home setting; bringing IGALMI[®] directly to patients in the at-home setting; use of IGALMI in approximately 70% of schizophrenia and bipolar disorder patients, regardless of agitation severity; prescribers using IGALMI either alone or in combination with existing off-label treatments for acute agitation; IGALMI replacing benzodiazepines, which may cause dependence; broad formulary coverage of IGALMI with standard adjudication controls; patients with schizophrenia and bipolar disorder using IGALMI in approximately 80% of their acute agitation episodes; evaluating go-to-market options; reimagining existing medicines and accelerating the development of innovative therapies; transforming the standard of care in neuropsychiatry and improve lives around the world. When used herein, words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; the impact of the reprioritization; its significant indebtedness, ability to comply with covenant obligations and potential payment obligations related to such indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY program; its dependence on the success and commercialization of IGALMI[®], BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; the number of episodes of agitation and the size of the Company’s total addressable market may be overestimated, and approval that the Company may obtain may be based on a narrower definition of the patient population; its lack of experience in marketing and selling drug products; the risk that IGALMI[®] or the Company’s product candidates may not be accepted by physicians or the medical community in general; the Company still faces extensive and ongoing regulatory requirements and obligations for IGALMI[®]; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company’s product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; the significant influence of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from data breaches or cyber-attacks, if any; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; risks associated with federal, state or foreign health care “fraud and abuse” laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the caption “Risk Factors” in its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC’s website at and the Investors section of the Company’s website. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this press release.

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.

Date: February 12, 2026

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
By: Richard Steinhart
Title: Chief Financial Officer
