

**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): September 10, 2025

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 September 10, 2025, BioXcel Therapeutics, Inc. (the “Company”) announced positive topline exploratory efficacy data from SERENITY At-Home Pivotal Phase 3 safety trial for agitation associated with bipolar disorders or schizophrenia

The SERENITY At-Home study is a Pivotal Phase 3, double-blind, placebo-controlled, 12-week clinical trial designed to evaluate the safety of BXCL501 (120 mcg dose) for the acute treatment of agitation associated with bipolar disorders or schizophrenia in an at-home setting. The trial also included an exploratory objective of assessing the continued efficacy of BXCL501 in the treatment of episodes of agitation.

SERENITY At-Home Topline Summary

- A total of 246 patients randomized
- Data collected on 2,628 agitation episodes in 215 patients over a 12 week period
 - o Treated 2,437 episodes in 208 patients
 - o 168 patients (81%) completed the full 12-week trial
 - o Average of 11.7 agitation episodes recorded per treated patient
 - o Reported agitation episodes were classified as mild (664), moderate (1,369) or severe (395)
- All patients were able to successfully self-administer the film
- Distribution of enrolled patients was 45% bipolar disorders and 55% schizophrenia
- Protocol allowed for concomitant interventions to self-regulate or manage agitation episodes

SERENITY AT-Home Topline Exploratory Efficacy Results

The efficacy of IGALMI® has already been established in the institutional setting in the SERENITY I and II trials that led to the approval by FDA (see label). In addition to the primary objective of evaluating the safety of BXCL501, the SERENITY At-Home trial also had an exploratory objective of assessing continued efficacy of BXCL501 with repeat dosing. The trial was not powered for these assessments. The positive results demonstrated continued effects and consistent benefits with repeat dosing of BXCL501, reinforcing the potential of BXCL501 in the outpatient setting.

Effect Across Total Number of Agitation Episodes

Across 2,433 treated episodes in the trial, BXCL501 demonstrated a significant mean reduction in the modified Clinical Global Impression–Severity (mCGI-S) score from baseline compared to placebo at 2 hours ($p < .05$).

Effect Across Severity of Agitation Episodes

Patients experienced a complete resolution of agitation symptoms measured by mCGI-S at significantly higher rates with BXCL501 compared to placebo across severity of agitation episodes, with an overall resolution of 50% in the BXCL501 arm, compared to 33% on placebo ($p < .0001$). Severe agitation episodes fully resolved (no agitation) in 61% of episodes in the BXCL501 arm, compared to 18% on placebo ($p < .0001$). Moderate agitation episodes fully resolved in 43% of cases for patients in the BXCL501 arm, compared to 34% on placebo ($p = .0005$). Mild agitation episodes fully resolved in 60% of cases for patients in the BXCL501 arm, compared to 40% on placebo ($p < .0001$). In sum, complete resolution of agitation was significantly higher with BXCL501 compared to placebo regardless of agitation episode severity.

Effect Across Number of Treated Agitation Episodes

The mean reduction in agitation symptoms experienced by patients following administration of BXCL501 was maintained throughout repeated dosing in the trial. There was a mean reduction in mCGI-S score of 1.2 following the first 12 doses and a mean reduction of 1.4 following 13 or more doses of BXCL501. This underscores the potential of BXCL501 to continue to provide benefit across repeated dosing.

Efficacy Across Duration of the Trial

The reduction in agitation symptoms experienced by patients following administration of BXCL501 was also maintained throughout the trial's duration. Evaluating the 12-week trial period on a time-based scale, agitation episodes treated with BXCL501 during weeks 1-4, 5-8 and 9-12 all had a mean reduction in mCGI-S score of 1.3. This underscores the potential of BXCL501 to maintain a sustained benefit across longer treatment durations.

IGALMI® is currently FDA-approved and marketed for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in medically supervised settings. IGALMI® is available in 2 dose strengths, 120 mcg and 180 mcg. To support the potential label expansion for at-home use, an important component of the regulatory package will be data from the SERENITY At-Home Pivotal Phase 3 trial. The trial design and protocol were previously agreed to with FDA.

BXCL501 was granted Fast Track Designation for the acute treatment of agitation associated with bipolar disorders or schizophrenia in December 2018. There are no FDA-approved therapies for the acute treatment of agitation in the at-home setting.

At-Home Agitation Market Insights

- The Company believes the total addressable market is significantly higher (57-77M agitation episodes annually) than previously anticipated (23M agitation episodes annually).
 - The previous estimate of 23M annual episodes was based on historic claims data, reflecting approximately 1.2 episode per patient per month. The claims data likely underestimate the actual episode frequency due to the lack of approved treatment options.
 - Market research and published survey data indicate that episodes may occur 3-4 times a month on average, with the majority of these episodes being moderate or severe.
 - Data from more than 2,600 episodes of agitation recorded in the SERENITY At-Home Pivotal Phase 3 trial are in line with these higher frequency estimates.
 - Physicians believe a significant unmet need is the lack of an effective and fast acting treatment at-home.
 - Physicians underdiagnose and undertreat these episodes in a community setting, with only a third of patients receiving prescription drugs, which are off-label and often suboptimal, for their agitation symptoms.
 - Patients are the primary stakeholder for the treatment of their agitation episodes.
 - Patients feel that they lack control over their thoughts and actions during agitation episodes.
 - In a market survey, patients indicated they would take BXCL501 for 80% of their agitation episodes.
 - 90% of those patients indicated they would take BXCL501 when they feel an episode coming on or when an episode begins.
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Forward-Looking Statements

This current report 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 other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: the Company’s upcoming top-line data release for the SERENITY At-Home Phase 3 trial, the planned sNDA submission, bringing a safe and effective outpatient treatment to patients suffering from agitation and transforming the treatment paradigm. 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 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 or potential of misuse of the Company’s product candidates that could impact regulatory approval; its novel approach to the discovery and development of product candidates based on EvolverAI or our AI platform; the significant influence of and dependence on BioXcel LLC; failure to maintain compliance with Nasdaq’s listing standards; 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 the factors discussed under the caption “Risk Factors” in its most recent Quarterly Report on Form 10-Q, as such factors may be updated from time to time in its other filings with the SEC. 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 current report. 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 current report.

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: September 10, 2025

BIOXCEL THERAPEUTICS, INC.

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