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) **October 4, 2023**

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38410**	**82-1386754**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS 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 7.01 Regulation FD Disclosure.

On October 4, 2023, BioXcel Therapeutics, Inc. (the "Company") provided the following business updates:

Late-Stage Clinical Programs: TRANQUILITY and SERENITY III

Agitation Associated with Mild to Moderate Dementia due to Probable Alzheimer's Disease ("AAD"):

Type B/Breakthrough Meeting on October 11

The Company plans to review its TRANQUILITY clinical trial program with the U.S. Food and Drug Administration ("FDA") and to discuss the data package required to support submission of an sNDA for the approval of BXC501 for the acute treatment of agitation in mild to moderate dementia patients with probable Alzheimer's disease in assisted living facilities and at-home settings.

The briefing book submitted to FDA for the meeting includes results from 11 double-blind, placebo-controlled, Phase 2 and 3 clinical trials evaluating the safety and efficacy of BXCL501. Trials with BXCL501 have enrolled more than 1,100 patients across multiple neuropsychiatric conditions and in healthy volunteers, and have shown no unexpected safety signals, no reports of serious adverse events or falls related to the study drug, and no drug-related deaths, which is all consistent with the known pharmacological effects of BXCL501.

Of the subjects who received various doses of BXCL501, 273 were over 60 years of age, and 204 were over 65 years of age. The TRANQUILITY I and TRANQUILITY II trials were placebo-controlled, showed statistically significant separation from placebo in Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score at two hours with the 60 mcg dose (primary endpoint), and had no unexpected safety findings. Data from TRANQUILITY I led the FDA to grant BXCL501 Breakthrough Therapy designation for the acute treatment of agitation associated with dementia. Additionally, the efficacy results seen in TRANQUILITY II after 12 weeks for all treated episodes was comparable to those observed after the first dose. Moreover, the adverse events ("AEs") observed after the first dose were similar to the AEs observed after all doses in TRANQUILITY II (443 episodes treated) and comparable to the AEs observed in the single-dose TRANQUILITY I trial (100 episodes treated).

Ongoing Investigation and Third Party Audit in Connection with TRANQUILITY II Trial

The Company is continuing its previously disclosed investigation into protocol adherence and data integrity at a principal investigator's trial site in connection with the TRANQUILITY II trial, and an independent third party is auditing the data collected at that site. The Company's ongoing investigation and/or the independent audit may result in findings regarding the integrity of the trial data from this principal investigator's site, the accuracy of safety or efficacy findings, or the usability of the data in connection with a marketing application. Even if the Company's investigation and the independent audit conclude that data from the trial have not been affected or compromised by the principal investigator's actions or other deficiencies at the trial site, the FDA may not accept or agree with the Company's conclusions or analyses, or may interpret or weigh their importance differently and the Company may be unable to use some or all of the subject data generated at this clinical site to support a marketing application. The Company can provide no assurance regarding the timing of the completion of its own investigation or the independent audit of the trial site or the FDA's views regarding the integrity of the data generated by the subject principal investigator for the TRANQUILITY II trial.

At-Home Setting in Agitation Associated with Bipolar Disorders I and II and Schizophrenia:

Type C Meeting on November 8

The Company will review its SERENITY III program with the FDA on November 8, 2023 and plans to discuss the data package required to support submission of an sNDA seeking approval of BXCL501 for the acute treatment of agitation associated with bipolar disorders I and II and schizophrenia in the at-home setting. In addition, the Company plans to discuss the evaluation of the 80 mcg dose of BXCL501 and several potential protocol amendments to the SERENITY III Part 2 trial. The Company identified the 80 mcg dose as more favorable for further development based on pharmacokinetic-pharmacodynamic (PK-PD) modeling anchored by extensive data from studies that evaluated the 60 mcg dose of BXCL501 (half of the lower approved IGALMI™ dose) as well as studies that evaluated the 120 mcg and 180 mcg approved doses of IGALMI™.

The primary objective of Part 2 of SERENITY III is to assess safety (the incidence of treatment-emergent adverse events), and the secondary objectives include various efficacy assessments.

IGALMI™ Market Exclusivity Strengthened: Two Notices of Allowance Received

BioXcel Therapeutics recently received two NOAs[1] from the U.S. Patent and Trademark Office for patent applications related to the method of use of sublingual dexmedetomidine for the treatment of agitation associated with bipolar disorders and schizophrenia. When these patents are granted, the Company plans to list them in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") for IGALMI™. The Company now has four U.S. patents claiming formulations of dexmedetomidine with exclusivity until 2039 currently listed in the Orange Book. The Company expects that these two new patents will expire no earlier than Dec. 29, 2037, subject to the patent term adjustment, patent term extension, and terminal disclaimers. These patents further broaden the scope of intellectual property estate for IGALMI™ and for future potential indications.

Forward-Looking Statements

This Current Report on Form 8-K ("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 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this Form 8-K other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements regarding: the Company's expected timing and outcome of discussions with FDA; the potential outcomes of the Company's investigation and third-party audit of a principal investigator's site; the Company's advancement of its product candidates for regulatory approval; and the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates, including the results from the TRANQUILITY II and SERENITY III clinical trials. The words "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; its ability to successfully negotiate amended terms under the financing agreements to be able to access funding and to obtain relief under financial covenants; its significant indebtedness and potential payment obligations related to such indebtedness and other contractual obligations; risks associated with the strategic reprioritization; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY II Phase 3 trial and related audit; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 BXCL701 and BXCL702 and other product candidates; 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 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; impacts from the COVID-19 pandemic; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, which is accessible on the Securities and Exchange Commission's website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. 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 Form 8-K.

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: October 4, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart

Title: Chief Financial Officer