

**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) **December 12, 2023**

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
(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 8.01 Other Events.

On December 12, 2023, in connection with its previously announced Research and Development Day, BioXcel Therapeutics, Inc. (the “Company”) provided an update on its clinical development pipeline, which is now as follows:

R&D Strategy: Build Pipeline Depth with Innovation and Expansion

Pipeline as of December 12, 2023

Compound	Indication/Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Marketed
 Igalmi. <small>(pilocarpinetartrate)</small>	<u>APPROVED APRIL 5, 2022</u> Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults under provider supervision						
BXCL501	<u>TRANQUILITY PROGRAM</u> Acute treatment of agitation in Alzheimer's dementia						
	<u>SERENITY III PROGRAM</u> Acute treatment of agitation in bipolar disorders/schizophrenia						
	Opioid Use Disorder (OUD)						
	Post Traumatic Stress Disorder (PTSD)						
BXCL502	Neuropsychiatric symptoms Chronic agitation in Alzheimer's dementia						
Candidate BXCL503	Apathy in dementia						
Candidate BXCL504	Aggression in dementia						

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established



In addition, on December 12, 2023, the Company announced that it had received the final minutes from its meeting with the U.S. Food and Drug Administration (“FDA”) held on November 8, 2023. Based on the feedback from the FDA meeting, the Company plans to evaluate BXCL501 in the at-home setting for the acute treatment of agitation in bipolar disorders and schizophrenia using a 120 mcg dose, with safety as the primary endpoint and with efficacy evaluations as exploratory endpoints.

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 regarding its clinical development pipeline and future clinical trials. 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 need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 and BXCL503 and other 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 September 30, 2023](#), 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 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: December 12, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer
