

**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 19, 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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 19, 2023, BioXcel Therapeutics, Inc. (the “Company”) announced that it had received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application related to the method of use of sublingual dexmedetomidine for the treatment of agitation associated with bipolar disorder. A Notice of Allowance is issued after the USPTO makes a determination that a patent should be granted from an application. Once granted, the Company plans to list the patent in the U.S. Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for IGALMI™. The Company has four U.S. patents currently listed in the Orange Book and, as recently reported, received a Notice of Allowance for a patent application, which relates to the method of use of sublingual dexmedetomidine for the treatment of agitation associated with schizophrenia that the Company also expects will be listed in the Orange Book. The patent issuing from this current notice should expire no earlier than December 29, 2037, subject to the patent term adjustment, patent term extension, and terminal disclaimers.

## **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 expectations regarding the patent issuance and listing in the Orange Book. 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, the important factors discussed under the caption “Risk Factors” in its Quarterly Report on Form 10-Q for the quarterly period ended June 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](http://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.

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**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 19, 2023

**BIOXCEL THERAPEUTICS, INC.**

/s/ Richard Steinhart

By: Richard Steinhart

Title: Chief Financial Officer

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