# 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 7, 2024**

# 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 8.01 Other Events.**

On February 5, 2024, BioXcel Therapeutics, Inc. (the "Company") announced that the United States Patent and Trademark Office ("USPTO") had allowed U.S. Patent Application No. 17/496,470 with claims pertaining to a method of treating agitation in patients with Alzheimer's disease using the oromucosal administration of 60 mcg of dexmedetomidine in a water-soluble dosage form. The broad claims encompass film formulations such as BXCL501 (sublingual dexmedetomidine), tablets, or wafers. The patent, when issued, is expected to have an expiration date of December 29, 2037, subject to patent term adjustment ("PTA"), patent term extension ("PTE") and terminal disclaimers.

The Company also announced on February 5, 2024, that it had received an issue notification from the USPTO for U.S. Patent Application No. 17/993,422, from which U.S. Patent No. 11,890,272 (the "'272 Patent") was issued on February 6, 2024. The '272 Patent claims a method of treating agitation associated with schizophrenia or bipolar disorder through oromucosal administration of about 120 mcg to about 180 mcg of dexmedetomidine where the patient has a QT interval of less than 470 msec. The '272 Patent has an expiration date of July 17, 2040, subject to PTA, PTE and terminal disclaimers. The '272 Patent has been accepted for listing in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book").

On February 7, 2024, the Company received notice that the USPTO had allowed U.S. Patent Application No. 18/216,890 with claims pertaining to a method of treating agitation using an oromucosal formulation of dexmedetomidine or a pharmaceutically acceptable salt thereof through the administration of an initial dose of 60 mcg, 80 mcg, 90 mcg, 120 mcg or 180 mcg of dexmedetomidine and, after at least two hours, administering an oromucosal formulation of dexmedetomidine or a pharmaceutically acceptable salt thereof in a second dose of 40 mcg, 60 mcg, 80 mcg or 90 mcg of dexmedetomidine, where the patient has a QT interval of less than 470 msec. The patent, when issued, is expected to have an expiration date of July 17, 2040, subject to PTA, PTE and terminal disclaimers. The Company expects that this patent, when issued, will be submitted for listing in the Orange Book with the eight currently listed U.S. patents for IGALMI™ (dexmedetomidine) sublingual film. Collectively, these nine patents will in general extend patent protection for IGALMI until January 12, 2043.

**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 patent issuances 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 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: February 8, 2024

**BIOXCEL THERAPEUTICS, INC.**

/s/ Javier Rodriguez

By: Javier Rodriguez

Title: SVP, Chief Legal Officer