

**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 28, 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
(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.

TRANQUILITY II Phase 3 Trial – FDA Inspection Update

On March 3, 2025, the Company announced that the U.S. Food and Drug Administration has concluded that the inspection of a single site in its TRANQUILITY II Phase 3 trial is closed under 21 C.F.R. 20.64(d)(3) and released the Establishment Inspection Report. The FDA has designated “Voluntary Action Indicated” for the site, which means objectionable conditions or practices were found, but the agency is not prepared to take or recommend any administrative or regulatory action.

SERENITY At-Home Pivotal Phase 3 Trial Update

In September 2024, the Company initiated patient enrollment in its SERENITY At-Home pivotal Phase 3 trial, evaluating the safety of BXCL501, the Company’s investigational, proprietary, orally dissolving film formulation of dexmedetomidine, in the at-home setting for the acute treatment of agitation associated with bipolar disorders or schizophrenia. As of February 28, 2025, 23 clinical trial sites have been opened and are enrolling patients.

Topline data results, which are expected in the second half of 2025, are intended to support a supplemental new drug application (sNDA) submission to potentially expand the label of IGALMI® (dexmedetomidine) sublingual film.

Nasdaq Update

On February 28, 2025, the Company received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC confirming that the Company has regained compliance with the minimum closing bid price requirement under Nasdaq Listing Rule 5550(a)(2).

Chief of Product Development and Medical Officer Resignation

On February 28, 2025, Vincent J. O’Neill, M.D. resigned as Executive Vice President, Chief of Product Development and Medical Officer of the Company.

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: March 3, 2025

BIOXCEL THERAPEUTICS, INC.

/s/ Javier Rodriguez
Javier Rodriguez
Chief Legal Officer
