

**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): August 27, 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
(I.R.S. 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 27, 2025, BioXcel Therapeutics, Inc. (the “Company”) announced that the SERENITY At-Home Pivotal Phase 3 trial evaluating the safety of BXCL501, the Company’s proprietary, sublingual film formulation of dexmedetomidine, as an acute treatment for agitation associated with bipolar disorders or schizophrenia in the at-home setting, met its primary endpoint. The SERENITY At-Home Pivotal Phase 3 trial is a double-blind, placebo-controlled 12 week trial designed to evaluate the safety of a 120 mcg dose of BXCL501 for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting. The data from this successful study will form the basis of the sNDA submission for label expansion of IGALMI® in the at-home setting planned for the first quarter of 2026.

SERENITY At-Home Topline Summary

- Summary of agitation episodes:
 - A total of 246 patients randomized
 - Data collected 2628 agitation episodes in 215 patients
 - Treated 2437 episodes in 208 patients
 - 168 patients (81%) completed the full 12-week trial
 - Average of 11.7 agitation episodes recorded per treated patient
- All patients were able to successfully self-administer the film
- Distribution of enrolled patients was 45% bipolar disorders and 55% schizophrenia

SERENITY AT-Home Primary Endpoint Data

The 120 mcg dose of BXCL501 was well-tolerated in patients with episodes of agitation in the outpatient setting and met the primary objective. This tolerability outcome was observed across repeat dosing and through the duration of the trial.

- No discontinuations due to tolerability in the BXCL501 arm
- Adverse event profile consistent with approved IGALMI® label and multiple clinical trials in the institutional setting
 - o No drug-related serious adverse events (SAEs), syncope or falls reported
 - o No new or unexpected treatment emergent adverse events (TEAEs)
 - o No severe TEAEs associated with BXCL501 treatment and most TEAEs were mild
 - o No trend of more frequent AEs over time or with repeat dosing
- Tolerability remained consistent throughout the repeat dosing in the trial

BXCL501 120 mcg Tolerability Profile Consistent with IGALMI® Label

	Serenity I & II (IGALMI® Label ¹)		Serenity At-Home Adverse Event by Dose (Episode) ¹			
	Single Dose		First Dose		All Doses (2437 episodes)	
	IGALMI® N=255 n (%)	Placebo N=252 n (%)	BXCL501 N=102 n (%)	Placebo N=106 n (%)	BXCL501 N=1160 n (%)	Placebo N=1277 n (%)
Treatment-Emergent Adverse Events ²						
Somnolence ³	56 (22%)	16 (6%)	23 (22.5%)	18 (17%)	161 (13.9%)	103 (8.1%)
Oral Paresthesia/Hypoesthesia	14 (6%)	2 (1%)	2 (2.0%)	1 (0.9%)	6 (0.5%)	1 (0.1%)
Dizziness	10 (4 %)	2 (1%)	5 (4.9%)	1 (0.9%)	19 (1.6%)	2 (0.2%)
Dry mouth	19 (7%)	3 (1%)	7 (6.9%)	1 (0.9%)	56 (4.8%)	24 (1.9%)
Nausea	6 (2%)	4 (2%)	1 (1.0%)	0(0%)	6 (0.5%)	1 (0.1%)
Headache	12 (5%)	12 (5%)	0 (0%)	2 (1.9%)	4 (0.3%)	4 (0.3%)

¹ SERENITY I and II evaluated a single agitation episode in each patient. SERENITY AT-Home evaluated a total of 2437 episodes in 208 patients. Adverse events are presented on an episode basis. Only AEs observed in Serenity At-Home Pivotal Phase 3 trial are listed

² AEs within 24 hours following dosing

³ Includes fatigue

BXCL501 Tolerability Profile Consistent with Repeat Dosing¹

	Doses 1-3		Doses 4 to 12		Doses 13 and beyond	
	BXCL501 N=266 n (%)	PLACEBO N=274 n (%)	BXCL501 N=398 n (%)	PLACEBO N=485 n (%)	BXCL501 N= 496 n (%)	PLACEBO N=518 n (%)
Treatment-Emergent Adverse Event ²						
Somnolence ³	58 (22.0%)	43 (16.0%)	61 (15.3%)	52 (10.8%)	42 (8.5%)	8 (1.5%)
Oral Paresthesia/Hypoesthesia	4 (1.5%)	1 (0.4%)	2 (0.5%)	0 (0%)	0 (0%)	0 (0%)
Dizziness	10 (3.8%)	1 (0.4%)	7 (1.8%)	1 (0.2%)	2 (0.4%)	0 (0%)
Dry mouth	14 (5.3%)	2 (0.7%)	29 (7.3%)	2 (0.4%)	13 (2.6%)	20 (3.9%)
Nausea	1 (0.4%)	1 (0.4%)	3 (0.8%)	0 (0%)	2 (0.4%)	0 (0%)
Headache	3 (1.1%)	2 (0.7%)	0 (0%)	2 (0.4%)	1 (0.2%)	0 (0%)

¹Adverse events are presented on an episode basis

²AEs within 24 hours following dosing

³Includes fatigue

BXCL501 Tolerability Profile Consistent over the Trial Duration¹

	Weeks 1 to 4		Weeks 5 to 8		Weeks 9 to 12	
	BXCL501 N=454 n (%)	PLACEBO N=474 n (%)	BXCL501 N=369 n (%)	PLACEBO N=433 n (%)	BXCL501 N=337 n (%)	PLACEBO N=370 n (%)
Treatment-Emergent Adverse Event ²						
Somnolence ³	74 (16.4%)	53 (11.2%)	47 (12.7%)	29 (6.7%)	36 (10.7%)	19 (5.2%)
Oral Paresthesia/Hypoesthesia	6 (1.3%)	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Dizziness	13 (2.9)	2 (0.4%)	3 (0.8%)	0 (0%)	3 (0.9%)	0 (0%)
Dry mouth	25 (5.5%)	2 (0.4%)	20 (5.4%)	10 (2.3%)	11 (3.3%)	12 (3.3%)
Nausea	3 (0.7%)	1 (0.2%)	2 (0.5%)	0 (0%)	1 (0.3%)	0 (0%)

¹Adverse events are presented for agitation episodes in the weeks indicated

²AEs within 24 hours following dosing

³Includes fatigue

SERENITY At-Home Preliminary Exploratory Data

The efficacy of IGALMI® has already been established in the institutional setting in the SERENITY I and II trials that led to FDA approval (see label). The available topline data for the exploratory endpoints from more than 2400 episodes in SERENITY At-Home demonstrates that treatment with BXCL501 regularly reduced symptoms of agitation throughout the trial. A greater percentage of patients experiencing mild, moderate, or severe agitation had full resolution of symptoms in the BXCL501 arm compared with placebo. The initial results demonstrate continued effects and consistent benefit with repeat dosing across the course of the trial.

Complete analyses of the full data set is ongoing, and results will be shared in the near future.

At-Home Agitation Market Insights

- The Company's previous estimate of 23 million annual episodes was based on historic claims data, reflecting approximately 1.2 episode per patient per month. The claims data likely underestimate the true episode frequency due to the lack of approved treatment options.
- Market research and published survey data indicate that episodes may occur 3-4 times a month on average, with the majority of these episodes being moderate or severe.
- Data from more than 2600 episodes of agitation recorded in the SERENITY At-Home Pivotal Phase 3 trial are in line with these higher frequency estimates.
- Based on these higher frequency estimates, the Company believes patients experience an estimated 57 million to 77 million agitation episodes in the at home setting annually in the United States.
- Physicians believe a significant unmet need is the lack of an effective and fast acting treatment at-home.
- Physicians underdiagnose and undertreat these episodes in a community setting, with only a third of patients receiving prescription drugs, which are off-label and often suboptimal, for their agitation symptoms.
- Patients are the primary stakeholder for the treatment of their agitation episodes.
 - Patients feel that they lack control over their thoughts and actions during agitation episodes.
 - In a market survey, patients indicated they would take BXCL501 for 80% of their agitation episodes.
 - 90% of those patients indicated they would take BXCL501 when they feel an episode coming on or when an episode begins.

Forward-Looking Statements

This current report includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company 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 and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this current report other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: the Company's planned advancement of its SERENITY program; potential market opportunity for BXCL501; release of data from the SERENITY At-Home trial; the submission of an sNDA to the FDA; the supply of IGALMI® through existing distribution channels; the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidate. 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 the factors discussed under the caption "Risk Factors" in its most recent Quarterly Report on Form 10-Q, as such factors may be updated from time to time in its other filings with the SEC. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this current report. 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 current report.

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: August 27, 2025

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
By: Richard Steinhart
Title: Chief Financial Officer
