

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): November 10, 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:

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 November 10, 2025, BioXcel Therapeutics, Inc. (the “Company”) announced that the Company’s poster entitled “BXCL501 (Sublingual Dexmedetomidine) for Treatment of Agitation Associated With Bipolar Disorder or Schizophrenia in the Home Setting: a Phase 3 Study” was presented at the Neuroscience Education Institute Conference on November 7, 2025 by Dr. Leslie Citrome.

A copy of the poster is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

Ex. No. **Description**

[99.1](#) [BXCL501 Poster](#)

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document

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: November 10, 2025

BIOXCEL THERAPEUTICS, INC.

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



BXCL501 (Sublingual Dexmedetomidine) for Treatment of Agitation Associated With Bipolar Disorder or Schizophrenia in the Home Setting: a Phase 3 Study

Leslie Citrome¹, Lavanaya Rajachandran², Robert Risinger³, Michael De Vivo², Heather Robison², Dusan Kostic², Matt Mandel², Rashmi Deshpande², Frank Yocca⁴
¹New York Medical College, ²BioXcel Therapeutics, Inc., ³BioXcel Therapeutics, Inc. (former), ⁴BioXcel Therapeutics, BioXcel Corporation



Introduction

- Patients with schizophrenia or bipolar disorder frequently experience episodes of agitation.
- In the home setting, where most episodes of agitation occur, there are no FDA-approved therapies for this indication.
- BXCL501 is a sublingual film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist, which has been approved for treatment of agitation under the supervision of a healthcare provider. A Phase 3 safety trial of BXCL501 was initiated with the goal of expanding the indication into the unsupervised (home) setting.

Methods

- A randomized, double-blind, placebo-controlled, Phase 3, 12-week trial (SERENITY At-Home, NCT05658510) in the home setting
- The primary outcome measure of the trial was the incidence of serious adverse events (SAEs) and treatment-emergent adverse events (TEAEs), defined as adverse events occurring within 24 hours of dosing.
- An exploratory objective was to evaluate whether repeated dosing would continue to provide treatment benefit. The exploratory outcome measures included a modified clinical global impression – severity (mCGI-S), scored by patients and by caregivers/informants, if present, on a scale of 0 (no agitation) to 3 (severe agitation)
- Patients could also use meditation, alcohol, cannabis, OTC medications etc. to reflect real-world coping strategies

INCLUDED PATIENTS

- Male and female patients ages 18–75 years with bipolar I or II disorder, schizophrenia, schizoaffective, or schizophreniform disorder
- On a stable psychotropic regimen for >30 days prior to screening
- History of ≥3 agitation episodes in past 3 months

EXCLUDED PATIENTS

- Unstable or serious medical illness (e.g., CHF, recent MI, hepatic disease)
- Diagnosis of antisocial, borderline, or narcissistic personality disorder that predated schizophrenia or bipolar disorder
- Moderate to severe substance use disorder in past 6 months
- Agitation due primarily to acute intoxication or substance use

Results

- 246 patients randomized
 - 31 patients had no recorded episodes over 12 weeks
 - 7 patients did not take study treatment for their episodes
- 2437 agitation episodes were treated in 208 patients
- 81% of treated patients completed the study

Primary Outcome: Safety and Tolerability

- At home, adverse events frequencies with a single dose were similar to those observed under medical supervision in previously completed Phase 3 studies (Table 1)
- Over repeated administration, the incidence of adverse events did not increase (Tables 1 and 2)
- No patient in the active arm discontinued due to TEAE

Table 1: Most common TEAEs in SERENITY At-Home and comparison with studies done under medical supervision

Treatment-Emergent Adverse Event	SERENITY I & II ¹		SERENITY AT-HOME Adverse Event by Dose (Episode) ¹			
	SINGLE DOSE BXCL501 120 MCG (N=255) n (%)	PLACEBO (N=252) n (%)	FIRST DOSE BXCL501 120 MCG (N=127) n (%)	PLACEBO (N=199) n (%)	ALL DOSES BXCL501 120 MCG (N=1169) n (%)	PLACEBO (N=1277) n (%)
Somnolence ²	56 (22%)	16 (6%)	23 (22.5%)	18 (17.0%)	161 (13.9%)	103 (8.1%)
Oral Paresthesia/Hypoesthesia	14 (6%)	2 (1%)	2 (2%)	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%)

¹SERENITY I and II evaluated a single-agent approach in the acute setting. SERENITY AT-Home evaluated a total of 1437 episodes in 208 patients. Adverse events are presented on an episode basis. ²Incidence of TEAE events per dosing episode.

Table 2: TEAEs per dosed episode by dose numbers

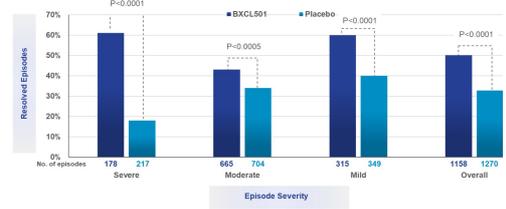
Treatment-Emergent Adverse Event	After Doses 1-3		After doses 4 to 12		After doses 13 and beyond	
	BXCL501 (N=260) n (%)	PLACEBO (N=274) n (%)	BXCL501 (N=260) n (%)	PLACEBO (N=403) n (%)	BXCL501 (N=450) n (%)	PLACEBO (N=113) n (%)
Somnolence ³	58 (22.0%)	43 (16.0%)	61 (15.3%)	52 (10.8%)	42 (8.5%)	8 (1.5%)
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%)

³Incidence of TEAE events per dosing episode.

Exploratory Outcome: Efficacy

- Although not powered for efficacy, the reduction in mCGI-S score was greater in the active group compared with placebo (P<0.05)
- There was a mean reduction in mCGI-S score of 1.2 following the first 12 doses and a mean reduction on following 13 or more doses of BXCL501, indicating no attenuation of benefit with repeat dosing.
- Complete resolution of agitation was significantly higher with BXCL501 compared to placebo across all episode severity (P<0.0001, Figure 1)

Figure 1: Percent of fully resolved episodes by baseline severity and overall



Conclusions

- In this pivotal safety study, sublingual dexmedetomidine 120 mcg was safe and well tolerated over a 12-week treatment period when administered on an as-needed basis
- Over repeat dosing, no increase in TEAEs was observed
- The reduction in symptoms remained consistent throughout the duration of the trial
- Significantly more patients experienced full resolution of agitation symptoms with BXCL501 than with placebo