

**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 11, 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 August 11, 2025, BioXcel Therapeutics, Inc. (the “Company”) posted a presentation on its website regarding BXCL501’s commercial opportunity related to the upcoming study results from the SERENITY At-Home Phase 3 trial, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Forward-Looking Statements

Exhibit 99.1 attached hereto contain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation dated August 11, 2025.
104	Cover Page Interactive Data File (embedded within 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: August 11, 2025

BIOXCEL THERAPEUTICS, INC.

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



BXCL501 Commercial Opportunity in the At-Home Setting for Bipolar Disorders and Schizophrenia

August 2025

BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | www.bioxccltherapeutics.com

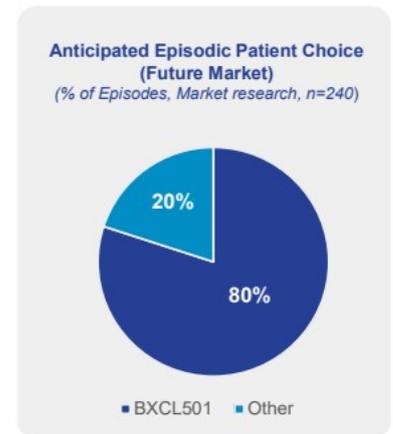
NASDAQ: BTAI



The At-Home Market for BXCL501 in Schizophrenia and Bipolar Disorders: Summary

The potential for BXCL501 in the at-home setting reflects significant unmet need and attractiveness to patients

- **Our market research indicates approximately 3 episodes of agitation per month in the home setting**
 - Previous estimate of 23M annual episodes was based on historic claims data (~1.2 episodes per month)
 - Due to the lack of approved treatment options, the claims data likely underestimate the true episode frequency
 - Consequently, the total addressable market (TAM) is significantly higher than previously reported
- **Based on the target product profile, HCPs indicated that they would treat ~16% of their patients with BXCL501**
- **HCPs believe that the most significant unmet need is the lack of effective and fast-acting treatments for the at-home setting**
- **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, which occur approximately three times per month on average
 - Patients want to treat the episode as soon as it begins and before it escalates in severity
- **Patients research suggests that they would use BXCL501 in 80% of the episodes experienced at-home**
- **Pricing flexibility in the market may allow up to \$1,400+ per prescription**
- **Attractive market access factors**



Agitation Characteristics

A behavioral emergency with highly variable clinical definitions and diagnoses¹⁻³



Agitation is characterized by¹



Emotional signs and symptoms

- Hyperresponsiveness
- Racing thoughts
- Emotional tension



Behavioral signs and symptoms

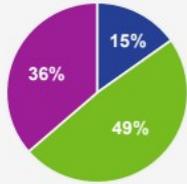
- Inability to stay calm or still
- Motor and verbal hyperactivity
- Communication impairments

1. Martinez-Raga J, et al. *Front Psychiatry*. 2018;9(54).
2. Roppolo LP, et al. *J Am Coll Emerg Physicians Open*. 2020;1(5):898-907.
3. Zeiler SL, Rhodes WP. *Clin Ther*. 2010;32(3):403-425.

Episode Frequency in Patients Experiencing Agitation

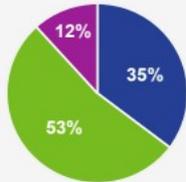
Agitation episodes expected to occur 3-4 times per month based on multiple data sources

Primary Market Research (N=80)¹



Schizophrenia (n=20)
35 Episodes per year
(~3/month)

■ Mild ■ Moderate ■ Severe



Bipolar Disorder (n=60)
38 Episodes per year
(~3/month)

■ Mild ■ Moderate ■ Severe

Published Survey (N=583)²

Severity	Number of episodes/year
Mild	22.4
Moderate	15.4
Moderate-intense	6.8
Severe	2.9
Total	47.5 (~4/month)

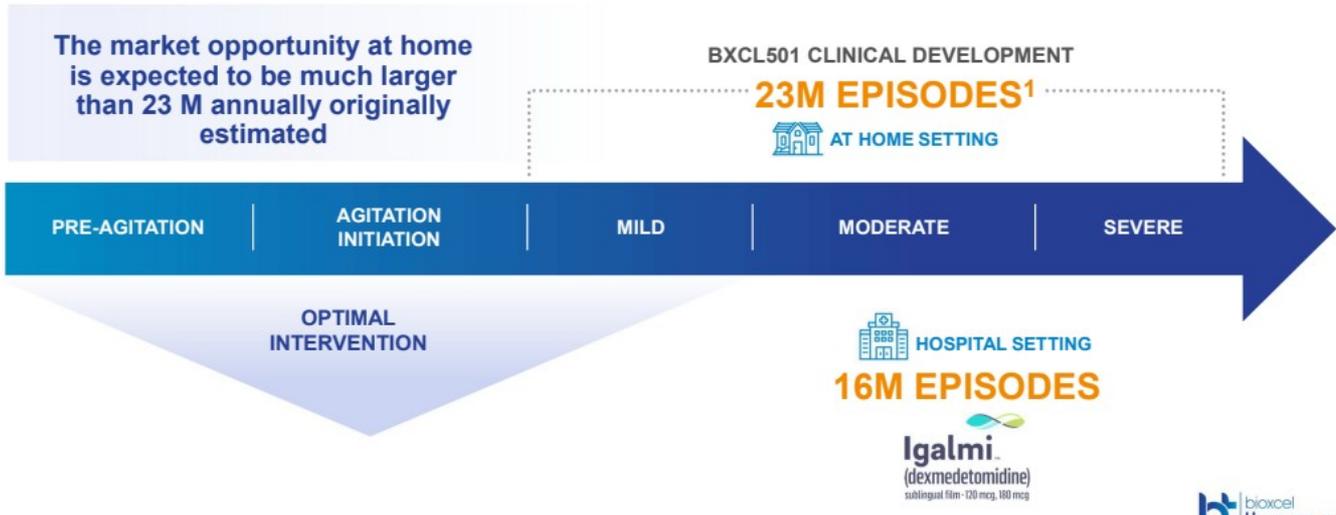
BXCL501 Serenity at Home Pivotal Phase 3 Trial

Data from more than 2,200
episodes collected

¹Source: InVivo Feb 2023 Q4: In the past month, about how many agitation episodes [F PATIENT SHOW 'have you' F CG SHOW 'has your loved one'] experienced?
Q5: Of the [Q4] agitation episodes you experienced in the past month, how many would you categorize as mild, moderate, or severe?
²Roberts et al. BMC Psychiatry (2018) 18:104

At-Home Intervention: Early Intervention May Prevent Severity Escalation

Potentially reduced ER visits, hospitalizations, or first responder interventions

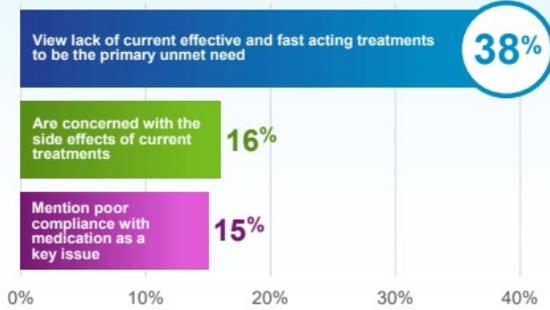


¹Number of schizophrenia/bipolar patients with agitation: Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Number of episodes per patient: Symphony claims data

Agitation as an Unmet Need

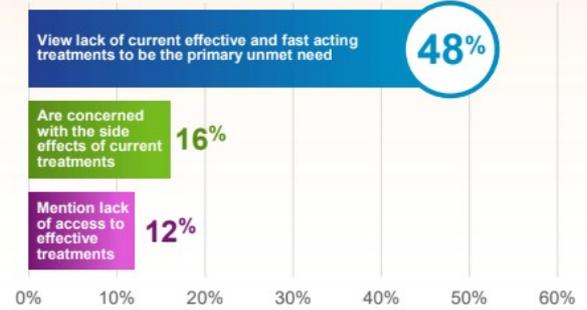
Market seeks effective, fast-acting, more tolerable treatment for agitation in bipolar and schizophrenia agitation for at-home use

Key unmet needs in BP



“ The available drugs either work too slowly or have unacceptable side effects.”
– Psychiatrist

Key unmet needs in SCZ



“ Other than the sedative effects of antipsychotics there really aren't any good options for managing agitation without just making the patient drowsy.”
– Psychiatrist

Source HCP Demand Study Oct 2022 Quantitative research n=90

HCP Preference Estimate

HCPs view lack of effective, tolerable, and fast acting treatments to be the primary unmet need; in addition, no products are currently approved in the at-home setting

Agitation associated with	BXCL501 Peak Market Share Based on Target at-home Product Profile
Bipolar Disorder & Schizophrenia	~16%

Allocation exercise assumptions:

- Percent of last 100 adult patients with breakthrough agitation seen the community setting who would receive BXCL501
- "Community setting" = patients seen in:
 - ✓ Provider office, clinic, outpatient mental health center, assisted living facility and supportive housing
- 10 films per prescription

Methodology:

Current Management: Respondents provide information about their patients and the treatment of each indication, including: Perceived unmet need, Estimated patient insurance mix, Guidelines used in treatment, Involvement of patients' caregivers

Current Allocation: Respondents estimate their current use of pharmaceutical treatments in the last 100 episodes of acute agitation for each indication.

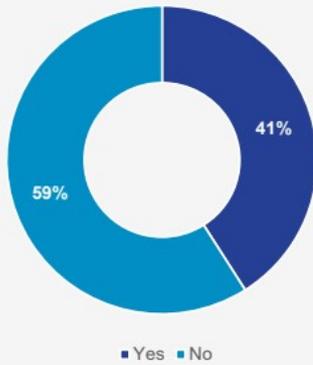
BXCL501 Evaluation: Respondents review the BXCL501 TPP for each indication and evaluate: Their perception of the profile, The patient types best suited for BXCL501, The likelihood of prescribing BXCL501 in the future

Future Allocation: Respondents repeat the allocation exercise assuming BXCL501 is available (in low and high doses for AD) in the following scenarios: Independent of cost sharing, Preferred Tier, Non-preferred Tier

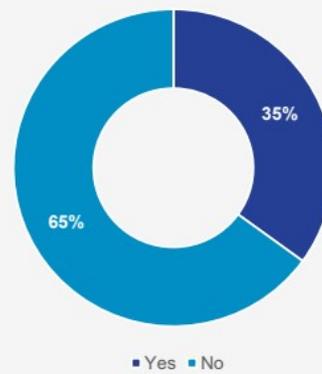
Recognition and Treatment of Agitation

Patients experiencing agitation indicate that they are not typically diagnosed, nor treated, for this symptom. This creates an opportunity and need for HCP education and market conditioning.

Agitation Diagnosis
(% of Total PT/CGs, n=80)



Prescribed a Treatment for Agitation
(% of Total PT/CGs, n=80)



Q1. Have you ever been diagnosed with agitation specifically? This can be a related but separate diagnosis to other mental health conditions
Q2. Have you ever been prescribed a treatment specifically for agitation episodes?
Q3. What was the treatment you were prescribed for agitation episodes?
Source: InVibe Feb 2023

Patients Perspectives of At-Home Agitation

Difficult for patients to articulate; patients feel a sense of helplessness

Overall Quality Descriptors



- Beyond their control
- Different from ordinary fear and anger.
- Feeling a lack of agency over their own thoughts and actions
- Likely to escalate
- Emotional experience of agitation likely makes it harder to make concrete, proactive decisions on when to seek help



Patient Quote

CLICK FOR VOICE



[I]t feels like there's something inside of me telling me **there's something wrong**, and I can't sit still, and I feel like my body's about to jump out of my skin. It's just really annoying, and **you get short-tempered** because of it and angry and snappy at people. **It's hard to describe** because you can't get it to go away, and it's just there, and **you're stuck with it**, and **there's nothing you can do** to make it go away."

(Q1, R10, PT, SCZ)

Question 1: Take a moment to describe what it is like to experience an episode of agitation associated with schizophrenia or bipolar disorder. How do you (or your loved one) feel during these times, both physically and emotionally?
Source: InVibe July 2022

Patient Aura

Patients experience a prodromal phenomenon with agitation incidents, which increases with episode severity.

Advance Knowledge of Agitation Episodes

(% of Episodes, n=240*)



* These data are compiled from 3 episodes described by each patient (N=80 pts/cgs *3 = 240)

Caregivers and patients were equally likely to have advance knowledge of an episode (22% for both groups)

Episode Intervention Target

Patients indicate that they want to manage the episode with BXCL501 either just before or at the first sign of escalation in the at-home setting.

Best Time To Take Igalmi
(% PTs/CGs n=80)

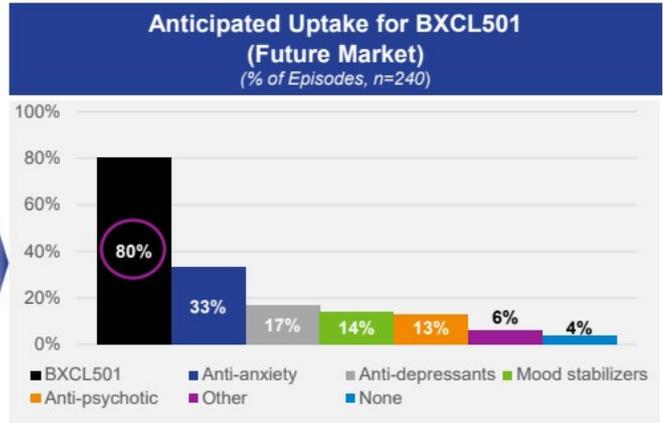
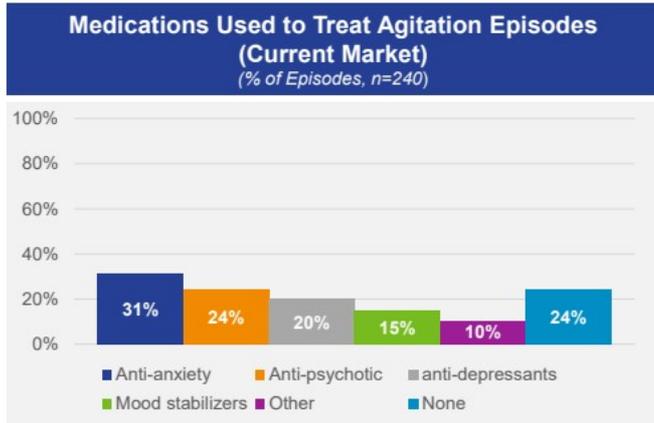


“I would love to be able to have it available **when I knew an episode was coming**. That it would help bite it in the butt, so to say. That would be such a benefit for me.”
(VR4, R8, PT, BPD, age 57)

Source: InVibe Feb 2023

Patients Preference Estimate

Based on a target product profile, patients say they would use BXCL501 for 80% of their episodes



Source: InVibe Feb 2023

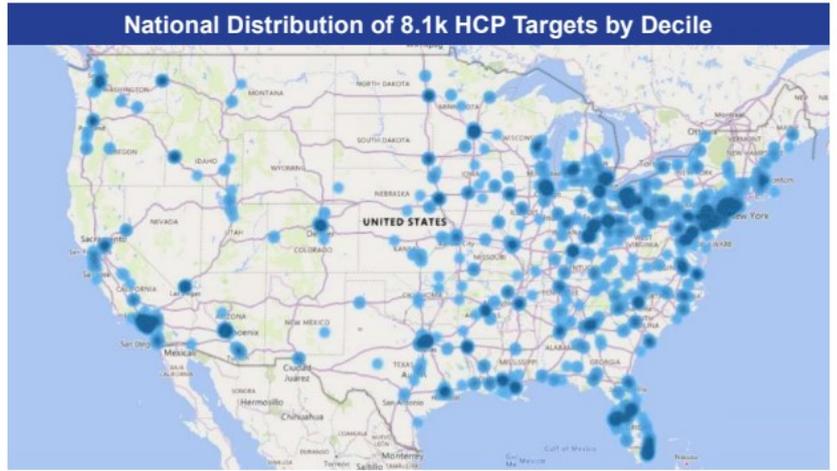
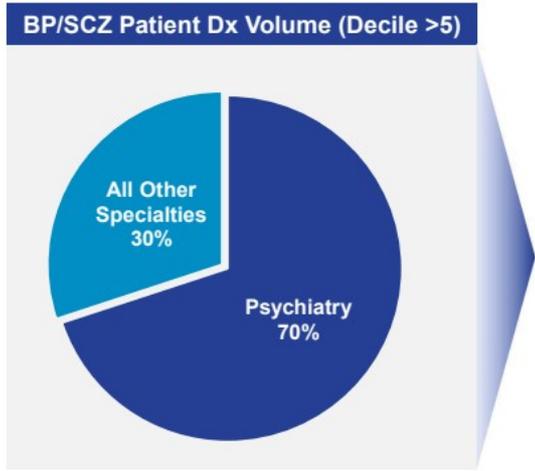
Retail Agitation Markets & Pricing Considerations

Current and development agitation products (chronic) cost over \$1400/month. These products have community psychiatry indications in Major Depressive Disorder as well, demonstrating pricing elasticity in psychiatric retail markets.



Provisional Targeting Model

Among the highest deciles of Bipolar & Schizophrenia patient Dx volume, 70% are managed by psychiatrists, with 8.1k total HCP targets. 50-70 discrete field FTEs can cover these targets



Sources: Clarivate Claims, FY2021; Definitive December 2022

Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. BioXcel Therapeutics, Inc. ("BioXcel" or the "Company") intends 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 presentation other than statements of historical fact should be considered forward-looking statements. 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 important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as such factors may be updated from time to time in its other filings with the SEC, including without limitation its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, 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 presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. 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 the Company's 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 presentation.

Industry and Other Data

Unless otherwise indicated, information contained in this presentation concerning our industry and the markets in which BioXcel Therapeutics operates, including its general expectations, market position and market opportunity, is based on its management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. While BioXcel Therapeutics believes the information from these third-party publications, research, surveys and studies is reliable, it does not guarantee the accuracy or completeness of such information, and BioXcel Therapeutics has not independently verified this information. Management's estimates are derived from publicly available information, their knowledge of the company's industry and their assumptions based on such information and knowledge, which they believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in BioXcel Therapeutics' periodic reports filed with the SEC under the captions "Forward Looking Statements," "Risk Factor Summary" and "Risk Factors." These and other factors could cause BioXcel Therapeutics' future performance and market expectations to differ materially from its assumptions and estimates.

