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): May 15, 2026

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)**	**(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 2.02 Results of Operations and Financial Condition.

On May 15, 2026, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2026 and provided a business update. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Ex. No.	**Description**
99.1	Press release, dated May 15, 2026.
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: May 15, 2026

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart

Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Provides Business Update and Reports First Quarter 2026 Financial Results

FDA accepted sNDA for IGALMI® use in at-home (outpatient) setting; set Nov. 14, 2026, as PDUFA date

Advancing BXCL501 as a potential acute treatment for agitation associated with Alzheimer's dementia

Evaluating strategic options with an advisor to maximize shareholder value and advance the commercial and development plans for IGALMI

NEW HAVEN, Conn., May 15, 2026 — BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience, today provided a business update and reported financial results for the first quarter of 2026. In the quarter ended on March 31, the FDA accepted the Company's supplemental New Drug Application (sNDA) for IGALMI® for at-home use in the acute treatment of agitation associated with bipolar disorders or schizophrenia and assigned a PDUFA target action date of November 14, 2026.

"The first quarter was marked by tremendous progress, achieving a major regulatory milestone and developing the IGALMI commercial launch plan for the at-home setting," said Vimal Mehta, Ph.D., Chief Executive Officer of BioXcel Therapeutics. "We are very pleased with the recent approval of another product in Alzheimer's agitation, in an area adjacent to our focus on the acute treatment of agitation in Alzheimer's dementia with BXCL501. Our first-in-class mechanism has the potential to make a transformative impact on the lives of a large patient population in this disease area. We are actively pursuing strategic options to maximize shareholder value for the IGALMI franchise."

Strategic Options

- **Exploring Value-Maximizing Options:** The Company engaged MTS Health Partners as an advisor for evaluation of strategic options to maximize shareholder value and advance the commercial and development plans for IGALMI, which may include, but are not limited to, a sale of the Company, a merger or other business combination, a collaboration, joint venture, royalty or license agreement of all or a portion of our assets, a recapitalization or other financing transaction, or continued execution of our standalone operating plan. We have not made a decision to pursue any specific transaction or strategic option, no set timetable has been established for the completion of this process, and there can be no assurance that the process will result in any transaction or other particular outcome.

BXCL501 Late-Stage Clinical Programs

SERENITY Program

- **FDA Acceptance of IGALMI At-Home sNDA**: The FDA recently accepted the Company's sNDA seeking to expand the IGALMI label for the at-home treatment of acute agitation in bipolar disorder and schizophrenia. The FDA has assigned a PDUFA target action date of November 14, 2026, which, if approved, would represent the first FDA-approved treatment option for acute agitation associated with bipolar disorders or schizophrenia in the at-home setting.

- **Commercial Launch Readiness**: The Company has been preparing for the commercial launch and has developed a comprehensive launch plan, informed by a third-party market assessment highlighting a large total addressable market for IGALMI in the at-home setting. The Company recently hosted a virtual event, held by a covering analyst, to present the launch plans and discuss the market opportunity with investors.

TRANQUILITY Program

- **TRANQUILITY In-Care Phase 3 Trial**: The TRANQUILITY In-Care trial is designed as a double-blind, placebo-controlled study to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 for the acute treatment of agitation associated with Alzheimer's dementia. The Company remains focused on BXCL501's potential in this disease, supported by a favorable regulatory environment following a recent FDA approval in an adjacent indication, which is further reinforcing the need in this therapeutic area.

First Quarter 2026 Financial Results

Net revenue from IGALMI® was $206,000 for the first quarter of 2026, compared to $168,000 for the same period in 2025. The Company is focused on preparing for IGALMI's launch in the at-home setting and maintaining IGALMI's brand awareness with minimal commercial resources.

Cost of Goods Sold for the first quarter of 2026 was $283,000, compared to $14,000 for the same period in 2025. The increase in Cost of Goods Sold for the first quarter is primarily the result of higher charges for reserves for excess or obsolete inventory compared to the same respective period in 2025.

Research and Development (R&D) expenses were $3.0 million for the first quarter of 2026, compared to $4.6 million for the same period in 2025. The decreased expenses for the first quarter of 2026 were primarily due to the completion of the SERENITY At-Home pivotal Phase 3 safety trial in 2025.

Selling, General and Administrative (SG&A) expenses were $7.2 million for the first quarter of 2026, compared to $5.7 million for the same period in 2025. The increased costs for the first quarter of 2026 were primarily attributable to an increase in professional fees.

Net Loss: BioXcel Therapeutics reported an operating loss of $10.2 million and a net loss of $12.7 million for the first quarter of 2026, compared to an operating loss of $10.1 million and net loss of $7.3 million for the same period in 2025.

Cash and cash equivalents and restricted cash totaled $17.2 million as of March 31, 2026.

The Company remains in compliance with the covenants in its Credit Agreement.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience. Its wholly owned subsidiary, OnkosXcel Therapeutics, is focused on the development of medicines in immuno-oncology. The Company's drug re-innovation approach leverages existing approved drugs and/or clinically validated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. For more information, please visit bioxceltherapeutics.com.

About BXCL501

Outside of its approved indication by the U.S. Food and Drug Administration as IGALMI® (dexmedetomidine) sublingual film, BXCL501 is an investigational proprietary, orally dissolving film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist. BXCL501 is under investigation by BioXcel Therapeutics for the acute treatment of agitation associated with Alzheimer's dementia and for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in the at-home setting. The safety and efficacy of BXCL501 for these investigational uses have not been established. BXCL501 has been granted Breakthrough Therapy designation by the FDA for the acute treatment of agitation associated with dementia and Fast Track designation for the acute treatment of agitation associated with schizophrenia, bipolar disorders, and dementia.

About IGALMI® (dexmedetomidine) sublingual film

IGALMI® (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, that is placed under the tongue or behind the lower lip and is used for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not been studied beyond 24 hours from the first dose. It is not known if IGALMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.

- **Heart rhythm changes (QT interval prolongation)**. IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.

- **Sleepiness/drowsiness**. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.

- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full prescribing information at Igalmi.com.

About the SERENITY At-Home Phase 3 Trial

The SERENITY At-Home Phase 3 trial is a double-blind, placebo-controlled study 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 trial is designed to evaluate 200 patients with a history of agitation episodes residing at home either alone or with caregivers/informants. Patients are self-administering 120-mcg of BXCL501 or placebo when agitation episodes occur over the 12-week trial period, with safety data (adverse events) collected during the trial. In addition, patients or caregivers/informants will complete a modified global impression of severity (mCGIs) and a clinical global impression of change (mCGI-C) two hours after dosing as an exploratory endpoint to evaluate use in the outpatient setting.

About the TRANQUILITY In-Care Phase 3 Trial

The TRANQUILITY In-Care trial is designed as a double-blind, placebo-controlled study to evaluate the efficacy and safety of a 60-mcg dose of BXCL501 over a 12-week period for agitation associated with Alzheimer's dementia in the care setting. The trial is expected to enroll approximately 150 patients 55 years and older who have mild, moderate, or severe dementia with mini-mental state examination scores of 0 to 25 and who reside in skilled nursing facilities, memory care units, or assisted living facilities. Patients will self-administer 60-mcg of BXCL501 or placebo when episodic agitation episodes occur over the trial period. The primary endpoint is expected to be a change from baseline in the Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score at two hours post-first dose. Additional PEC and Clinical Global Impressions – Improvement Scale measurements will also be obtained during the trial.

Forward-Looking Statements

This press release 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 and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: approval by the FDA of the sNDA and expanded label for IGALMI, IGALMI’s ability to make a transformative impact on the lives of a large patient population, ability to advance a strategic option to maximize shareholder value and advance the commercial and development plans for IGALMI. 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: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; the impact of the reprioritization; its significant indebtedness, ability to comply with covenant obligations and potential payment obligations related to such indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY program; its dependence on the success and commercialization of IGALMI®, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; the number of episodes of agitation and the size of the Company’s total addressable market may be overestimated, and approval that the Company may obtain may be based on a narrower definition of the patient population; its lack of experience in marketing and selling drug products; the risk that IGALMI® or the Company’s product candidates may not be accepted by physicians or the medical community in general; the Company still faces extensive and ongoing regulatory requirements and obligations for IGALMI®; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company’s product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; the significant influence of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from data breaches or cyber-attacks, if any; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; risks associated with federal, state or foreign health care “fraud and abuse” laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the caption “Risk Factors” in its Annual Report on Form 10-K for the fiscal year ended December 31, 2025, 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 and the Investors section of the Company’s website at. 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 press release. 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 press release.

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Source: BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc.

Statements of Operations
(Unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2026	2025
Revenues		
Product revenues	$ 206	$ 168
Operating expenses		
Cost of goods sold	283	14
Research and development	2,955	4,554
Selling, general and administrative	7,191	5,699
Restructuring costs	-	-
Total operating expenses	10,429	10,267
Loss from operations	(10,223)	(10,099)
Other (income) expense		
Interest expense, net	4,198	3,993
Interest income	(211)	(279)
Other (income) expense, net	(1,519)	(6,559)
Net loss and comprehensive loss	$ (12,691)	$ (7,254)
Net loss per share - basic and diluted	$ (0.54)	$ (1.50)
Weighted average shares outstanding - basic and diluted	23,571	4,834

Condensed Balance Sheets
(Unaudited, in thousands)

	March 31, 2026	December 31, 2025
Cash and cash equivalents and restricted cash	$ 17,180	$ 28,757
Total assets	$ 34,025	$ 44,916
Total liabilities	$ 139,568	$ 140,379
Total stockholders' equity (deficit)	$ (105,543)	$ (95,463)