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 14, 2023

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 November 14, 2023, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2023 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.

Exhibit No.	**Description**
99.1	Press release, dated November 14, 2023
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 14, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Aligns with FDA Recommendation for Phase 3 Trial for TRANQUILITY Program, Provides Update on Strategic Financing, and Reports Third Quarter 2023 Financial Results

Company plans to conduct Phase 3 trial of BXCL501 in the at-home setting for TRANQUILITY program to support potential sNDA for acute treatment of agitation associated with dementia due to probable Alzheimer's disease

Potential market opportunity for BXCL501 to include acute treatment of agitation across full spectrum of Alzheimer's-related dementia and agitation severity across all care settings

Based on FDA feedback, Company plans to conduct Phase 3 trial with 120 mcg (IGALMI™ approved dose) in the at-home setting for SERENITY III program for acute treatment of agitation in bipolar disorders or schizophrenia

Key financial terms agreed with Oaktree Capital Management and Qatar Investment Authority to enhance operational and financial flexibility

Conference call and webcast set for 8:00 a.m. ET today

NEW HAVEN, Conn., Nov. 14, 2023 — BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced alignment with the FDA's recommendation for a Phase 3 trial in the TRANQUILITY program. In addition, the Company provided an update on strategic financing activities that would enable greater operational flexibility and reported its financial results for the third quarter ended Sept. 30, 2023.

"This is a time of tremendous progress and excitement for our company and stakeholders, especially as we report a clinical development path forward for our TRANQUILITY program," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "I am proud of the teamwork that enabled us to turn our focus to much larger potential opportunities for BXCL501 in at-home settings, beginning with agitation associated with Alzheimer's dementia. Furthermore, we believe FDA feedback in the recent meeting focused on the SERENITY III program provides a clear path to develop BXCL501 for at-home use in the treatment of agitation associated with schizophrenia and bipolar disorders. When we couple these positive developments with revised terms with our strategic financing partners, we believe we have a strong foundation to deliver success."

Progress on Two Late-Stage Clinical Programs

TRANQUILITY:

Evaluating potential use of BXCL501 for acute treatment of agitation associated with Alzheimer's dementia

- Received meeting minutes from October 11, 2023 FDA meeting.
- Company aligned with FDA's recommendation to conduct additional Phase 3 trial of BXCL501 to evaluate safety and collect additional efficacy data in at-home setting.

- Planned study expected to enroll approximately 100 patients aged 65 years and older with mild, moderate, or severe dementia who will self-administer 60 mcg of BXCL501 or placebo whenever agitation episodes occur over a four-week period.

- The long term safety requirement for submission will be discussed with the FDA based on the observed frequency of agitation
- TRANQUILITY III trial is no longer required for potential sNDA submission; Company plans to explore potential separate clinical development program for chronic agitation.

SERENITY III:

Evaluating potential at-home use of BXCL501 for agitation associated with bipolar disorders or schizophrenia

- Completed meeting with FDA on November 8, 2023; meeting minutes expected by the first half of December 2023.
- Based on FDA feedback, Company plans to conduct a Phase 3 trial with 120 mcg (IGALMI™ approved dose) to evaluate safety in at-home setting.
  - Since IGALMI's launch, the Company estimates more than 10,000 treatments (120 mcg or 180 mcg dose) have been administered; pharmacovigilance monitoring has revealed no new or unexpected safety events in clinical settings.

Strategic Financing Update: Oaktree Capital Management and Qatar Investment Authority

- Company entered into a binding term sheet to amend strategic financing agreements with Oaktree Capital Management and Qatar Investment Authority, subject to entry into definitive documentation. The term sheet provides for revised key financial terms that are expected to enhance the Company's operational and financial flexibility, including:
  - Revised terms that would increase the Company's potential to access additional tranches of capital under the agreements; and
  - Revised revenue covenant to extend the deadline for compliance and adjust covenant levels to reflect current projections (this is intended to reduce short-term cash outflows that would be required to cure the revenue covenant if not satisfied).
- Company secured waiver and modification to covenant regarding investments in OnkosXcel Therapeutics.

IGALMI™ Commercialization

- Building brand awareness through contracting approach as Company prepares for potential larger at-home market opportunities, if approved in such indications.
- Permanent IGALMI J-Code issued from Centers for Medicare & Medicaid Services expected to streamline reimbursement process across commercial and government payers.
- Patent protection extended up to 2043 with two new Orange Book-listed U.S. patents related to method of use of sublingual dexmedetomidine for treatment of agitation associated with bipolar disorders and schizophrenia.

OnkosXcel Therapeutics

- Reported positive overall survival results from open-label Phase 2 trial of BXCL701 in patients with metastatic castration-resistant prostate cancer of adenocarcinoma phenotype and in patients with small cell neuroendocrine prostate cancer.
- Focusing on strategic options for OnkosXcel Therapeutics, including potential financing, strategic partnership, or M&A.

Third Quarter 2023 Financial Results

Net Revenue: Net revenue of IGALMI was approximately $341,000 for the quarter.

Research and Development (R&D) Expenses: R&D expenses were $19.6 million for the third quarter of 2023, compared to $22.1 million for the same period in 2022. The decreased expenses were primarily attributable to a decrease in expenses associated with the BXCL501 SERENITY III and TRANQUILITY II clinical trials.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $24.3 million for the third quarter of 2023, compared to $17.1 million for the same period in 2022. The increased expenses were primarily attributable to an increase in one-time legal and professional fees, costs associated with the OnkosXcel potential public offering as well as in personnel, and related costs to support commercialization of IGALMI in the U.S. prior to the Reprioritization.

Net Loss: BioXcel Therapeutics had a net loss of $50.5 million for the third quarter of 2023, compared to a net loss of $41.8 million for the same period in 2022. The Company used $37.6 million in operating cash during the third quarter.

Cash and cash equivalents totaled $90.0 million as of September 30, 2023. The Company has entered into a binding term sheet to restructure key financial terms in its agreements with Oaktree Capital Management and Qatar Investment Authority to provide for enhanced operational and financial flexibility, including the potential to access additional tranches of capital. The Company estimates that its current cash and cash equivalents will fund its operations through mid-2024. This estimated cash runway does not include potential additional capital that may become available under the amendments to the strategic financing agreements or resulting from any potential financing activities that may be undertaken by the Company.

Conference Call and Webcast

BioXcel Therapeutics will host a conference call and webcast on Nov. 14, 2023, at 8:00 a.m. ET to provide an update on recent operational highlights and to discuss its third quarter 2023 financial results. To access the call, please dial 877-407-5795 (domestic) or 201-689-8722 (international). A live webcast will be available on the Investors section of the corporate website, bioxceltherapeutics.com, and a replay will be available through February 14, 2024.

BioXcel Therapeutics may use its website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investors sections of its website at www.bioxceltherapeutics.com. In addition, you may sign up to automatically receive email alerts and other information about the Company by visiting the “Email Alerts” option under the News/Events section of the Investors & Media website section and submitting your email address.

About IGALMI™ (dexmedetomidine) sublingual film

INDICATION

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 BXCL501

In indications other than those approved by the FDA as IGALMI™ BXCL501 is an investigational proprietary, orally dissolving film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist. BioXcel Therapeutics believes that BXCL501 potentially targets an important mediator of agitation, and the Company has observed anti-agitation results in multiple clinical studies across several neuropsychiatric disorders. BXCL501 is under investigation for the acute treatment of agitation associated with dementia due to probable Alzheimer's disease 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 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 BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience. 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.

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 regarding the Company's expected timing of, protocols for and data results from, trials and clinical studies involving its product candidates; potential market opportunity for BXCL501; the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates; its ongoing strategy for IGALMI; anticipated cost savings; expected cash runway and cash burn rates; the Company's expected refinancing of its strategic financing agreements; the expected outcomes of discussions with the FDA and paths to potential sNDA approval of BXCL501; strategic options for OnkosXcel; future access to capital; and the Company's future financial and operational results. 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," "when," "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; its ability to successfully enter into definitive documentation with its strategic financing lenders for amended terms under the financing agreements; its significant indebtedness and potential payment obligations related to such indebtedness and other contractual obligations; risks associated with the strategic reprioritization; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY II Phase 3 trial and related investigation; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; 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 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; impacts from the COVID-19 pandemic; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, 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 September 30, 2023, 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 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues				
Product revenues	$ 341	$ 137	$ 1,004	$ 137
Operating expenses				
Cost of goods sold	512	11	546	11
Research and development	19,619	22,062	74,392	58,780
Selling, general and administrative	24,344	17,054	73,810	48,097
Restructuring costs	4,163	-	4,163	-
Total operating expenses	48,638	39,127	152,911	106,888
Loss from operations	(48,297)	(38,990)	(151,907)	(106,751)
Other (income) expense				
Interest expense, net	2,184	2,877	5,176	4,251
Other expense (income), net	5	(62)	(286)	(53)
Net loss and comprehensive loss	$ (50,486)	$ (41,805)	$ (156,797)	$ (110,949)
Net loss per share - basic and diluted	$ (1.72)	$ (1.49)	$ (5.40)	$ (3.96)
Weighted average shares outstanding - basic and diluted	29,268	28,022	29,026	27,997

Condensed Balance Sheets
(Unaudited, in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 89,961	$ 193,725
Working capital	$ 59,330	$ 169,970
Total assets	$ 100,449	$ 205,853
Long-term liabilities	$ 101,649	$ 96,180
Total liabilities	$ 141,057	$ 129,078
Total stockholders' (deficit) equity	$ (40,608)	$ 76,775