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): March 12, 2024

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 March 12, 2024, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and year ended December 31, 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 March 12, 2024
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: March 12, 2024

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Financial Results for the Fourth Quarter and Full Year 2023

Provides update on two late-stage clinical programs for BXCL501 for potential treatment of agitation

Recently completed meetings with U.S. Food and Drug Administration for TRANQUILITY and SERENITY programs

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

NEW HAVEN, Conn., March 12, 2024 — BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience and immuno-oncology, today provided an update on its late-stage TRANQUILITY and SERENITY clinical programs. In addition, the Company reported its financial results for the fourth quarter and full year 2023.

"We believe our late-stage programs evaluating BXCL501 for acute agitation associated with Alzheimer's dementia, bipolar disorders, and schizophrenia represent groundbreaking opportunities to bring much-needed treatment options to large numbers of patients and caregivers," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "We are pleased to be advancing the clinical development paths for TRANQUILITY and SERENITY, and plan to focus our resources on these high-priority programs."

TRANQUILITY Program:

Evaluating 60 mcg dose of BXCL501 for agitation associated with Alzheimer's dementia (AAD)

- On February 20, 2024, the Company held a Type B/Breakthrough Therapy designation meeting with FDA.
- Based on the FDA's feedback, the Company plans to generate additional Phase 3 efficacy and safety data in care facilities to expand the database beyond the 70 patients who have already been treated with 60 mcg of BXCL501 in TRANQUILITY I and II to date. The Company plans to generate these data in a variety of relevant care settings and across severity of dementia using the Positive and Negative Syndrome Scale-Excitatory Component (PEC) as the primary efficacy measure, as used in the prior TRANQUILITY II study.
    - The Company announced in November 2023 that it was planning to conduct a Phase 3 trial in the at-home setting, with safety as the primary objective (TRANQUILITY At Home). Given the priority to expand the database to generate additional efficacy data in care facilities, the Company is re-evaluating the timing for initiating TRANQUILITY At Home.
- Given no prior regulatory precedent for episodic treatment of agitation in AD patients, the Company plans to engage with the FDA regarding the requirement for collection of long-term safety data.
- The Company expects to provide further guidance regarding program plans following receipt of final meeting minutes from FDA.

SERENITY Program:

Evaluating potential at-home use of 120 mcg of BXCL501 for agitation associated with bipolar disorders or schizophrenia

- On March 6, 2024, the Company held a Type C meeting with FDA.
- Based on FDA feedback, Company plans to conduct a Phase 3 trial by amending the SERENITY III protocol to evaluate the 120 mcg dose of BXCL501 (an approved dose of IGALMI™) in the at-home setting, with safety as the primary objective and efficacy measures as exploratory endpoints**.**
- The Company expects to provide further guidance regarding program plans following receipt of final meeting minutes from FDA.

Corporate Updates

IGALMI™ Commercialization

- Permanent J-Code for IGALMI™ (dexmedetomidine) sublingual film became effective Jan. 1, 2024; code helps to standardize the reimbursement process, simplify claims submission, and in turn streamline billing and reimbursement for customers.
- Dedicated Corporate Account Director (CAD) team has secured and continues to secure volume contracts, driving broader access to IGALMI™.

Patent Portfolio

The Company continues to develop a broad global intellectual property portfolio, with over 100 patent applications in prosecution and multiple patents issued as of February 29, 2024.

- Neuroscience franchise (BXCL501 and pipeline): Company’s patent portfolio includes 10 issued U.S. patents, with eight listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), as well as three patents from Japan and 11 patents from other countries. Additionally, the portfolio has 19 utility patent applications and seven provisional applications in the U.S. and 116 utility patent applications in other countries, as well as two Patent Cooperation Treaty (PCT) applications not yet in the national phase. The expiry dates for the Orange Book listed patents covering Igalmi in the U.S. run from December 29, 2037 to January 12, 2043.
- Immuno-oncology franchise (BXCL701 and pipeline): Company’s patent portfolio includes two issued patents in the U.S., one in Japan, and 12 in other countries, as well as one provisional application and six utility patent applications in the U.S., and 31 utility patent applications in other countries.

OnkosXcel Therapeutics

- FDA designated as a Fast Track development program the investigation of BXCL701 in combination with a checkpoint inhibitor for treatment of patients with metastatic small cell neuroendocrine prostate cancer (SCNC) with progression on chemotherapy and no evidence of microsatellite instability.

- Reported completion of patient enrollment in safety portion of Phase 2 relapsed pancreatic cancer trial of BXCL701 in combination with KEYTRUDA® sponsored by Georgetown Lombardi Comprehensive Cancer Center.

- Initiated formal process to assess strategic options.

Fourth Quarter and Full Year 2023 Financial Results

Net Revenue: Net revenue from IGALMI was $376,000 for the fourth quarter of 2023, compared to $238,000 for the same period in 2022.

Net revenue from IGALMI was $1.4 million for the full year of 2023, compared to $375,000 for 2022.

Research and Development (R&D) Expenses: R&D expenses were $9.9 million for the fourth quarter of 2023, compared to $32.5 million for the same period in 2022.

R&D expenses were $84.3 million for the full year of 2023, compared to $91.2 million for the full year of 2022. The decreased expenses for both the fourth quarter and the full year were primarily attributable to a decrease in clinical trial activity associated with the wind down of the SERENITY III and TRANQUILITY II studies, a decrease in chemical, manufacturing, and control (CMC) costs, and a decrease in personnel related to the Reprioritization.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $9.6 million for the fourth quarter of 2023, compared to $20.7 million for the same period in 2022.

SG&A expenses were $83.4 million for the full year 2023, compared to $68.8 million for 2022. The increased costs for the full year were primarily attributable to an increase in legal and professional fees, costs associated with increased personnel, and related costs to support the commercialization of IGALMI in the U.S. prior to the Reprioritization.

Net Loss: BioXcel Therapeutics had a net loss of $22.3 million for the fourth quarter of 2023, compared to a net loss of $54.8 million for the same period in 2022. For the full year of 2023, BioXcel Therapeutics reported a net loss of $179.0 million, compared to a net loss of $165.8 million for the full year of 2022. The loss for the 2023 year includes approximately $18.6 million in non-cash stock-based compensation. Total cash expenditures for 2023 totaled approximately $155.0 million.

Cash and cash equivalents totaled $65.2 million on December 31, 2023, compared to $193.7 million on December 31, 2022. 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 March 12, 2024, at 8:00 a.m. ET to provide an update on recent operational highlights and to discuss its fourth quarter and full year 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 June 12, 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 U.S. Food and Drug Administration (FDA) as IGALMI™ (dexmedetomidine) sublingual film, 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 trials across several neuropsychiatric disorders. BXCL501 is under investigation by BioXcel Therapeutics 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 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 the Positive and Negative Syndrome Scale-Excitatory Component Score (PEC or PANSS-EC)

The PEC total score is a validated endpoint for use in clinical research to quantify the severity of a patient's acute agitation. The PEC rating evaluates 5 elements associated with agitation: poor impulse control, tension, hostility, uncooperativeness, and excitement; each scored 1 (minimum) to 7 (maximum). The PEC total score is the sum of these 5 elements and thus ranges from 5 to 35.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence 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.

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 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; the Company's current patent applications; expected cash runway and cash burn rates; developments relating to the TRANQUILITY and SERENITY programs; and the expected outcomes of further discussions with the FDA. 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; 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; our estimates of episodes of agitation and total addressable market are subject to inherent challenges and uncertainties; 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, as such factors may be updated from time to time in its other filings with the SEC, including without limitation its Annual Report on Form 10-K for the fiscal year ended December 31, 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 December 31,		Year ended December 31,	
	2023	2022	2023	2022
Revenues				
Product revenues	$ 376	$ 238	$ 1,380	$ 375
Operating expenses				
Cost of goods sold	$ 714	$ 9	$ 1,260	$ 20
Research and development	$ 9,934	$ 32,459	$ 84,326	$ 91,239
Selling, general and administrative	$ 9,603	$ 20,664	$ 83,413	$ 68,761
Restructuring costs	$ -	$ -	$ 4,163	$ -
Total operating expenses	$ 20,251	$ 53,132	$ 173,162	$ 160,020
Loss from operations	$ (19,875)	$ (52,894)	$ (171,782)	$ (159,645)
Other (income) expense				
Interest expense, net	$ 3,435	$ 2,921	$ 13,314	$ 8,213
Interest income	$ (946)	$ (1,487)	$ (5,649)	$ (2,528)
Other (income) expense, net	$ (108)	$ 480	$ (394)	$ 427
Net loss and comprehensive loss	$ (22,256)	$ (54,808)	$ (179,053)	$ (165,757)
Net loss per share - basic and diluted	$ (0.76)	$ (1.95)	$ (6.15)	$ (5.92)
Weighted average shares outstanding - basic and diluted	29,449	28,068	29,129	28,015

Condensed Balance Sheets
(Unaudited, in thousands)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 65,221	$ 193,725
Total assets	$ 73,702	$ 205,853
Total liabilities	$ 130,210	$ 129,078
Total stockholders' equity (deficit)	$ (56,508)	$ 76,775