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) **February 13, 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)	(IRS 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 February 13, 2023, BioXcel Therapeutics, Inc. (the "Company") announced full data from its Phase 2a trial of BXCL701, the Company's investigational, oral innate immune activator, in combination with KEYTRUDA® (pembrolizumab) in small cell neuroendocrine (SCNC) variant metastatic castration-resistant prostate cancer (mCRPC) patients after at least one prior line of chemotherapy for locally advanced or metastatic prostate cancer. Results will be presented in a rapid abstract presentation and a poster presentation at the 2023 American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) Symposium on February 16, 2023.

KEY SCNC FINDINGS

- In the evaluable patient cohort (n = 28), 7 (25%) patients achieved a composite response, the primary endpoint of the trial.
- In patients with RECIST 1.1-defined measurable disease (n = 25), partial response (PR) was observed in 5 (20%) patients (4 confirmed PR, 1 unconfirmed PR). The disease control rate, defined as complete response + partial response + stable disease, was 48% (12 patients).
- The median duration of response for both composite responses and RECIST 1.1-defined partial responses was 6+ months as of the data cutoff on December 19, 2022.
- 6 out of 34 patients (18%) in the safety population experienced serious adverse events (SAEs) possibly related or related to BXCL701 or pembrolizumab, and 6 (18%) patients discontinued any drug due to a treatment-related AE.
- No evidence found that BXCL701 potentiates immune-related AEs related to immune checkpoint inhibitors.
- DPP9 overexpression was identified as a potential predictive biomarker for BXCL701 response; biomarker evaluation is ongoing and additional findings will be presented at an upcoming medical meeting.

The Phase 2a trial is an open-label, multicenter study to evaluate the safety and efficacy of BXCL701 in combination with pembrolizumab in men with SCNC. Eligibility criteria include histologically confirmed de novo or treatment-emergent SCNC, progression as defined by PCWG3 criteria, and at least 1 prior line of chemotherapy for locally advanced or metastatic prostate cancer. Twenty-eight (28) evaluable SCNC patients received 0.3 mg of BXCL701 twice daily (BID) on days 1 through 14 of a 21-day cycle (0.2 mg BID the first week of Cycle 1) plus 200 mg of pembrolizumab administered intravenously on day 1 and every subsequent 21 days. The primary endpoint of the trial is a composite response rate defined as either objective response by RECIST 1.1 criteria and/or PSA50 and/or CTC count conversion. Secondary endpoints include duration of response, progression-free survival, overall survival, and biomarker evaluation as measured by changes in circulating cytokines and correlation of outcome with baseline tumor characteristics. The Company intends to begin a randomized study of BXCL701 and pembrolizumab in the second half of 2023.

Forward-Looking Statements

This Current Report on Form 8-K ("Form 8-K") includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this Form 8-K other than statements of historical fact should be considered forward-looking statements, including, without limitation, the Company's expected timing of, trial design and data results from, future clinical trials of BXCL701 with pembrolizumab, the Company's presentation at ASCO GU and potential benefits from treatment with BXCL701. 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 experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 and BXCL701 and other product candidates; its limited experience in marketing and selling drug products; 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; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, 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 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 Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. 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 Form 8-K.

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: February 13, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart

Title: Chief Financial Officer