
**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 21, 2023**

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
(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:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|---------------------------------|--------------------------|--|
| 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 Information.

As previously announced, BioXcel Therapeutics, Inc. (the "Company"), hosted a BXCL701 Key Opinion Leader Day ("KOL Day") on Tuesday, February 21, 2023 from 1:00 to 3:00 p.m. Eastern Time. The Company's Chief Executive Officer, Vimal Mehta, Ph.D., and Chief Research and Development Officer of OnkosXcel Therapeutics, a wholly owned subsidiary of the Company, Vincent J. O'Neill, M.D., were joined by a panel of leading oncology experts to review top-line Phase 2 data results that were recently presented at the 2023 American Society of Clinical Oncology Genitourinary Cancers Symposium and the development path and future opportunities for BXCL701, which is currently being developed for the potential treatment of small cell neuroendocrine prostate cancer.

Select slides included in the presentation materials used at the KOL Day are filed as Exhibit 99.1 hereto and incorporated by reference herein.

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. 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 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements in the Form 8-K and appended slides include but are not limited to: statements regarding BioXcel Therapeutics' expected timing of, and data results from, trials and clinical studies involving its product candidates, in particular BXCL701; planned discussions with regulators and potential registrational trials; strategic options for OnkosXcel; and potential market size and opportunity for product candidates. The words "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 BioXcel Therapeutics' current expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel Therapeutics 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: the Company's limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; 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; the Company has limited experience in marketing and selling drug products; 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; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; 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 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 and the Investors section of our website at www.bioxceltherapeutics.com.

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 BioXcel Therapeutics 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 BioXcel Therapeutics' views as of any date subsequent to the date of this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

| Exhibit No. | Description |
|-----------------------------|---|
| <u>99.1</u> | <u>Slides from KOL Day, dated February 21, 2023.</u> |
| 104 | Cover Page Interactive Data File (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: February 21, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer



BXCL701 Key Opinion Leader Day

February 21, 2023

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

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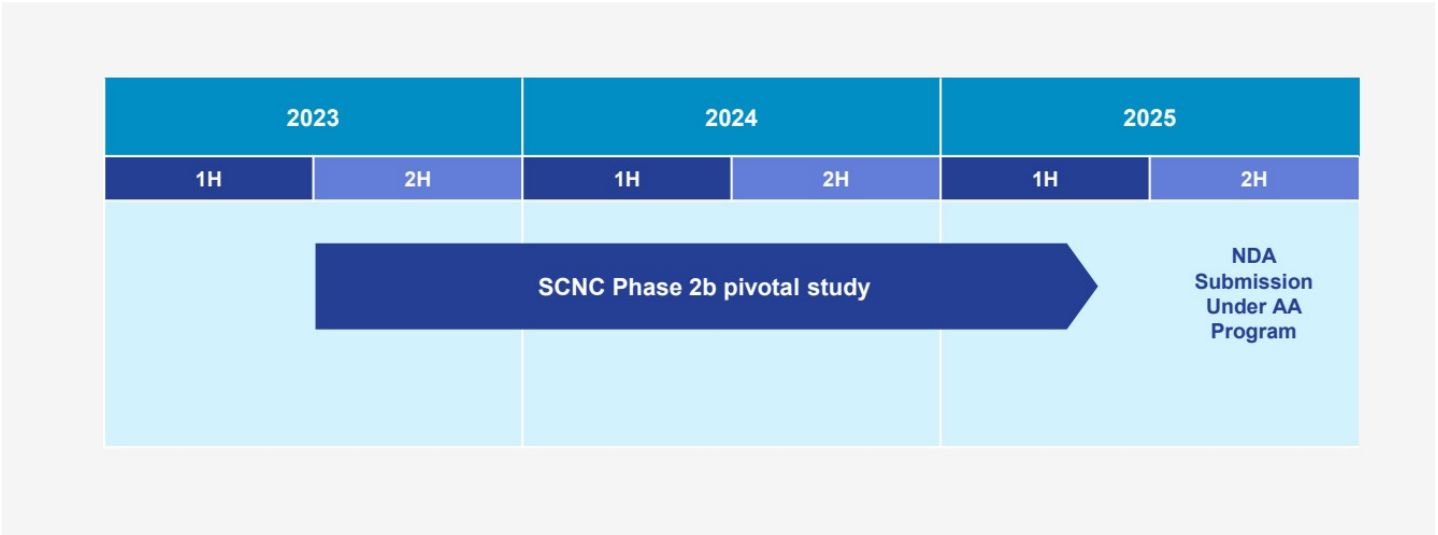


BXCL701: Pipeline Within a Product Plan and Next-Generation Candidate

| Compound | Proposed Indication | Preclinical | Phase 1 | Phase 2 | Expected Upcoming Milestone | Collaborator |
|---|--|-------------|---------|---------|--------------------------------------|--|
| BXCL701 | Small Cell Neuroendocrine Prostate Cancer (SCNC) | | | | Initiate Phase 2b | |
| | Small Cell Lung Cancer (SCLC) | | | | Initiate Phase 1b/2 | |
| | Acute Myeloid Leukemia (AML) IST* | | | | Initiate Phase 1b/2 | |
| | Metastatic Pancreatic Ductal Adenocarcinoma IST* | | | | Initiate Phase 2 | Georgetown Lombardi COMPREHENSIVE CANCER CENTER supply agreement |
| Next-Generation DPP8/9 Inhibitor | Solid and Liquid Tumors | | | | Initiate novel candidate development | |

*Investigator Sponsored Trial

SCNC Clinical Development Timeline*



*Initial discussions with the FDA regarding the development pathway and registrational strategy for BCXL701 in SCNC expected in mid-2023.
| AA = Accelerated Approval



SCLC Clinical Development Timeline

