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) August 10, 2021

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 August 10, 2021, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three and six months ended June 30, 2021 and other matters described in the press release. 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 August 10, 2021.

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: August 10, 2021

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Second Quarter 2021 Financial Results and Recent Operational Highlights

Phase 3 study of BXCL501 for the acute treatment of agitation associated with dementia expected to begin in Q4 2021

PDUFA date of January 5, 2022 assigned to BXCL501 NDA for the acute treatment of agitation associated with schizophrenia and bipolar disorders I & II

Data from adenocarcinoma cohort of Phase 1b/2 study of BXCL701 and KEYTRUDA® in aggressive forms of prostate cancer anticipated in Q3 2021

Raised gross proceeds of approximately $100 million with a common stock offering in June to further fund ongoing clinical development studies and commercialization readiness preparations

Company to host a conference call today, August 10, 2021 at 8:30 a.m. EDT

NEW HAVEN, Conn., August 10, 2021 -- BioXcel Therapeutics, Inc. ("BioXcel" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its financial results for the second quarter ended June 30, 2021 and provided an update on key strategic initiatives.

"During the second quarter, we continued to successfully execute across our clinical, regulatory and commercial objectives for our neuroscience candidate, BXCL501, including furthering our plans for the pivotal Phase 3 program in dementia, executing on our global expansion strategy, and advancing through the regulatory review process," said Vimal Mehta, Ph.D., CEO of BioXcel. "With acceptance of our NDA by the FDA, we are one step closer to our first-ever product approval and making this innovative therapy available to patients suffering from acute agitation associated with schizophrenia and bipolar disorders. We continue to advance our commercial readiness strategy, if approved, and in parallel are advancing our strategic plans for geographic expansion."

Dr. Mehta added, "Looking ahead, we remain confident in the broad potential of BXCL501 across multiple indications where there is significant need for innovative treatments. We remain on track to commence our Phase 3 program for the acute treatment of agitation associated with dementia in the fourth quarter of this year and are exploring additional pipeline opportunities as growth drivers for this business. Looking beyond our neuroscience program, our Phase 1/2b study of BXCL701 for castrate resistant prostate cancer is advancing well, with additional efficacy data from the adenocarcinoma cohort expected in the third quarter 2021. We look forward to building on these successes during the second half of this year."

Company Highlights

Neuroscience Program

BXCL501 is an investigational proprietary, orally dissolving, thin film formulation of the adrenergic receptor agonist dexmedetomidine for the treatment of agitation resulting from neuropsychiatric disorders

- Expect to commence the BXCL501 Phase 3 program for the acute treatment of agitation associated with dementia in Q4 2021, pending further feedback from the FDA.

- Plan to report topline data from the 40 mcg Phase 2 trial of BXCL501 in patients with acute agitation associated with dementia during Q4 2021.

- Received a Prescription Drug User Fee Act ("PDUFA") target action date of January 5, 2022 for the NDA for BXCL501 in the acute treatment of agitation associated with schizophrenia and bipolar disorders I & II.

- Plans are underway for a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA") of BXCL501 for the acute treatment of agitation associated with schizophrenia and bipolar disorders I & II in 2H 2021.

- Initiated pediatric study of BXCL501 for the acute treatment of agitation associated with schizophrenia and bipolar disorders I & II.

Commercial Highlights

- Held a Virtual Commercial Day on June 25, 2021, highlighting launch readiness plans in preparation for the potential approval of BXCL501 for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II.

- Continue to advance commercial readiness strategy for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II.

Medical Affairs Highlights

- Presented data from the BXCL501 Phase 3 trials (SERENITY I & II) at the American Psychiatric Association Annual Meeting and at the International Society for Bipolar Disorders 2021 Global Annual Conference and additional data will be presented at a leading medical conference in 2H 2021.

- Medical Science Liaison and Medical Manage Care teams continue to engage in scientific and medical-to-medical exchange with healthcare professionals and payers, respectively to provide key insights to support commercial strategy.

Immuno-Oncology Program

BXCL701 is an orally administered systemic innate immune activator for treatment of a rare form of prostate cancer and advanced solid tumors that are refractory or treatment naïve to checkpoint inhibitors.

- Data readout from the adenocarcinoma cohort of the Phase 1b/2 trial of BXCL701 and pembrolizumab (KEYTRUDA®) in aggressive forms of prostate cancer is planned for Q3 2021.

Corporate Highlights

- In June 2021, the Company raised gross proceeds of approximately of $100 million in a common stock offering, providing sufficient cash runway to further fund ongoing clinical development studies and commercialization readiness preparations.

Second Quarter 2021 Financial Results

Research and Development Expenses: Research and development expenses were $13.5 million during the second quarter of 2021, as compared to $17.9 million for the same period in 2020. The decreased expenses were primarily attributable to a reduction in our SERENITY clinical trial costs offset in-part by an increase in personnel and related costs necessary to enlarge our development and medical teams. In addition, we experienced greater professional fees primarily due to increased toxicology studies, regulatory fees and consulting fees, all related to BXCL501.

General and Administrative Expenses: General and administrative expenses were $14.1 million for the second quarter of 2021, as compared to $3.5 million for the same period in 2020. The increase was primarily due to higher stock-based compensation and personnel costs due to our continuing efforts to expand our teams as well as increased marketing and commercial costs related to our preparation of the potential commercial launch of BXCL501 in the U.S., as well as increased legal, professional fees, and insurance costs.

Net Loss: BioXcel reported a net loss of $27.6 million for the second quarter of 2021, compared to a net loss of $21.4 million for the same period in 2020.

The second quarter 2021 results include approximately $6.8 million in non-cash stock-based compensation costs, compared to non-cash stock-based compensation of $2.0 million for the same period in 2020. As of June 30, 2021, cash and cash equivalents totaled approximately $273.1 million.

Conference Call

BioXcel will host a conference call and webcast today at 8:30 a.m. EDT. To access the call, please dial 877-407-2985 (domestic) and 201-378-4915 (international). A live webcast of the call will be available on the Investors section of the BioXcel website, and a replay of the call will be available through at least August 25, 2021. BioXcel's website is available at www.bioxceltherapeutics.com.

BioXcel 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 automatically receive email alerts and other information about the Company when you enroll your email address by visiting the "Email Alerts" option under the News / Events menu of the Investors section of its website at www.bioxceltherapeutics.com.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. is a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. BioXcel'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 indices. BioXcel's two most advanced clinical development programs are BXCL501, an investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine for the treatment of agitation and opioid withdrawal symptoms, and BXCL701, an investigational, orally administered, systemic innate immunity activator in development for the treatment of aggressive forms of prostate cancer and advanced solid tumors that are refractory or treatment naïve to checkpoint inhibitors. For more information, please visit www.bioxceltherapeutics.com.

Forward-Looking Statement

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the timing and data from clinical trials for BXCL501 and BXCL701, the timing of potential commercial approval of BXCL501 for the acute treatment of schizophrenia and bipolar disorders I and II, the Company's planned commercial structure, the potential value of BXCL501 and BXCL701 as treatment options, the Company's geographic expansion program for BXCL501, including filing an MAA with the EMA, and future financial and operational results. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. 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 limited experience in drug discovery and drug development; its dependence on the success and commercialization of BXCL501 and BXCL701 and other product candidates; 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 approach to the discovery and development of product candidates based on EvolverAI is novel and unproven; 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 June 30, 2021, 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 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.

Contact Information

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Source: BioXcel Therapeutics, Inc.