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) **June 22, 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)	(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.

Recent Developments

Corporate Update

SERENITY I and SERENITY II

BXCL501, our proprietary sublingual thin film of dexmedetomidine, met the primary and secondary endpoints of SERENITY I and SERENITY II, demonstrating a robust treatment effect in the trials. Results demonstrated that BXCL501 was well tolerated, with rapid and durable reductions in agitation.

In patients with schizophrenia (SERENITY I) and a second study of bipolar disorder (SERENITY II), highly statistically significant and clinically meaningful reductions in the Positive and Negative Syndrome Scale, Excitatory Component ("PEC") score at two hours, the primary endpoint, were reported for both high and low dose cohorts of BXCL501 compared to placebo ($p<0.0001$). Both studies also met the key secondary endpoint, demonstrating improvement in PEC scores beginning as early as 20 minutes in patients with bipolar disorder, at both dose levels, and as early as 20 minutes in patients with schizophrenia for the 180 mcg dose level. Exploratory efficacy endpoints confirmed the primary endpoint, with duration of response lasting at least four hours after treatment.

***Summary of Results*:**

SERENITY I (Patients with Schizophrenia)

Effect at 120 minutes (Primary Endpoint)	**Placebo (n=126)**	**120 mcg (n=129)**	**180 mcg (n=126)**
Reduction in PEC Score vs. Baseline (LSM)	-4.8	-8.5 ($p<0.0001$)	-10.3 ($p<0.0001$)
Response Rate (% of Patients Achieving >40% Reduction in PEC Scores)	34%	79.1%	88.8%

SERENITY II (Patients with Bipolar Disorder*)

Effect at 120 minutes (Primary Endpoint)	**Placebo (n=126)**	**120 mcg (n=126)**	**180 mcg (n=126)**
Reduction in PEC Score vs. Baseline (LSM)	-5.0	-9.1 ($p<0.0001$)	-10.4 ($p<0.0001$)
Response Rate (% of Patients Achieving >40% Reduction in PEC Scores)	37%	77%	90.5%

*includes bipolar I and II disorder, with a diagnosis of depression, hypomania, mania, mixed episodes or unspecified

The secondary endpoint was highly statistically significant at 30 minutes, 45 minutes, 60 minutes, and 90 minutes in both studies. At 20 minutes, both doses were statistically significant in patients with bipolar disorder ($p<0.025$), and in patients with schizophrenia who received the higher 180 mcg dose.

Efficacy was further evaluated using two additional measures of agitation—the Agitation and Calmness Evaluation Scale ("ACES"), and Clinical Global Impression – Improvement Scale ("CGI-I")—each of which showed statistically significant improvements for both doses of BXCL501 compared to placebo.

BXCL501 was well tolerated in both SERENITY trials. Overall, the most commonly reported adverse events from both trials were somnolence (22% for 180 mcg dose arms, 21% for 120 mcg dose arms and 6% for placebo arms; >75% of these events were classified as mild), dry mouth (4.4%, 7.5% and 1.2%, respectively), and dizziness (6.0%, 3.9%, and 0.8%, respectively). All adverse events were mild to moderate in severity, with none categorized as severe or requiring further intervention or monitoring. Few subjects discontinued the trials due to adverse events (SERENITY I: 0 for 180 mcg dose, 2 for 120 mcg dose and 0 for placebo arm; SERENITY II: 0, 1, and 0, respectively). We believe that the robust data set from our Phase 3 SERENITY trials will form a solid foundation for our work in our other BXCL501 trials.

In October 2020, we held a pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") to discuss the content and format of our anticipated NDA submission. The FDA also agreed to a rolling review of our NDA, allowing us to submit completed sections of the application early. In March 2021, we completed the rolling submission of our NDA to the FDA. On May 19, 2021 we announced that FDA has accepted the NDA for filing and assigned a Prescription Drug User Fee Act target action date of January 5, 2022. We plan to submit a Marketing Authorization Application with the European Medicines Agency using SERENITY I and II data for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II in the second half of 2021.

TRANQUILITY

We evaluated BXCL501 in our TRANQUILITY trial, a phase 1b/2 randomized, placebo-controlled, adaptive ascending dose-finding study that enrolled 54 patients with agitation related to dementia. Patients received BXCL501 at either 30mcg (n=16), 60mcg (n=20), 90mcg (n=4) or placebo (n=14). Overall, BXCL501 was well tolerated and demonstrated statistically significant, clinically meaningful, rapid, and durable reductions in agitation with the 60 mcg dose as measured by multiple scales.

The trial's primary objective was to evaluate safety and tolerability. During the study, BXCL501 was well-tolerated and no severe or serious adverse events were reported. The most common adverse event was somnolence characterized as either mild (55% for 60 mcg, 56.3% for 30 mcg and 0% for placebo) or moderate (5% for 60 mcg and 0% for both 30 mcg and placebo), followed by hypotension (10%, 0%, 0%), orthostatic hypotension (5%, 6.3%, 0%) and dizziness (5%, 6.3% and 0%). There were no reported cases of syncope or falls in any of the patients studied. Higher exposure levels of BXCL501 were observed in this elderly patient population compared to earlier trials.

The trial met its secondary efficacy endpoints with the 60 mcg dose compared to placebo in all three agitation scales: the Positive and Negative Syndrome Scale-Excitatory Component ("PEC"); the Pittsburg Agitation Scale ("PAS"), and the Modified Cohen -Mansfield Inventory ("Mod-CMAI"). Treatment with BXCL501 demonstrated statistically significant and clinically meaningful reductions in total scores at two hours post-dosing (PEC $p=0.0011$; PAS $p<0.0001$; Mod-CMAI $p<0.0001$; PEC response rate = 70%; reduction in PAS score of 5.9 from baseline), numerical separation from placebo in PEC total score as early as 30 minutes with statistically significant reductions on both PEC and PAS at 60 minutes lasting 8 hours after treatment.

Additional statistically significant reductions with the 60 mcg dose compared to placebo at 2 hours post-dosing were observed with the Agitation and Calmness Scale (ACES $p=0.0006$) and Clinical Global Impression-Improvement Scale (CGI $p<0.0001$, 90% responder rate).

In March 2021, we announced that, following a routine quality control review of the Company's TRANQUILITY study data, the Company discovered that two patients were mis-categorized within the 30 mcg cohort at the clinical site. After moving the two patients into their appropriate placebo and 30 mcg groups, the data from the 30 mcg cohort were reanalyzed, resulting in the 30 mcg dose crossing over to statistical significance at the two hour time point, as measured by PEC: $p=0.0149$; PAS: $p=0.0195$; and Mod-CMAI: $p=0.0364$, with a PEC response rate = 31% and reduction in PAS score of 4.1 from baseline.

We announced that we initiated a 46 patient (1:1 randomization) multicenter, placebo-controlled TRANQUILITY expansion study investigating a 40 mcg dose cohort of BXCL501. PK/PD modeling of BXCL501 data from the TRANQUILITY trial was supportive of evaluating the efficacy of a 40 mcg dose. Recruitment in this study is progressing well. Results are expected to provide additional insights to support the Company's clinical development strategy directed at all segments of the dementia market.

In March 2021, we announced that we received FDA Breakthrough Therapy Designation for BXCL501 for the acute treatment of agitation associated with dementia. Breakthrough Therapy Designation is intended to expedite the development and review of investigational therapies that are designed to treat serious or life-threatening diseases or conditions.

We held an end of Phase 2 meeting with the FDA in May 2021 to discuss the BXCL501 program for the acute treatment of agitation in dementia patients. We plan to hold additional meetings with the FDA in the second half of 2021 in order to discuss certain matters, including the trial design, dosing regimen, and endpoints for the pivotal Phase 3 program. Although we expect to commence a Phase 3 trial in the second half of 2021, such commencement is subject to reaching alignment with the FDA on these matters.

Books and Record Demand

The Company has received a demand letter pursuant to Section 220 of the Delaware General Corporation Law ("DGCL") from a stockholder seeking disclosure of certain of the Company's records. The Company has responded to those demands, stating its belief that the demand letter fails to fully comply with the requirements of Section 220 of the DGCL. On June 15, 2021, the stockholder filed a complaint in Delaware Chancery Court seeking to compel inspection of books and records pursuant to Section 220 of the DGCL. The Company believes the claim is without merit and intends to vigorously defend against it.

Forward-Looking Statements

This Current Report on Form 8-K includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this Form 8-K include but are not limited to the timing and data from clinical development initiatives and trials for BXCL501, dialogue with the FDA and the future development of BXCL501, and the Company's corporate strategy. 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 BTI's current expectations and various assumptions. BTI believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BTI 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 BTI'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 March 31, 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* 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 Current Report on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Current Report on 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 the Company's 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 Current Report on 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: June 22, 2021

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer