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) **July 27, 2020**

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 2.02 Results of Operations and Financial Condition.

BioXcel Therapeutics, Inc. ("BTI" or the "Company") had cash and cash equivalents totaling $65.5 million as of June 30, 2020.

Item 8.01 Other Events.

We are providing the following business update.

Recent Developments

BXCL501 Neuroscience Program

On July 20, 2020, the Company announced that BXCL501, the Company's 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 Topline 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%	67%	87%

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%	69%	85%

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

The secondary endpoint was also statistically significant starting at 20 minutes ($p< 0.025$) for both doses in bipolar disorder patients and in the 180 mcg dose in schizophrenia patients. Both doses in both trials were highly statistically significant at 30 minutes, 45 minutes, 60 minutes, and 90 minutes following treatment.

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).

On July 9, 2020, BTI announced that it initiated an expanded access program at Massachusetts General Hospital to provide its investigational drug, BXCL501 to critically ill patients diagnosed with COVID-19 in the intensive care unit that may require calming or arousable sedation. Facilitated by the U.S. Food and Drug Administration, expanded access, also known as compassionate use, provides an opportunity for patients to receive an investigational treatment prior to regulatory approval when there are no comparable or satisfactory therapeutic alternatives available.

On July 7, 2020, the Company announced that it received a Notice of Allowance from the U.S. Patent and Trademark Office ("USPTO") for patent application No. 16/453,679 related to BXCL501. The patent is expected to cover film formulations containing Dex and methods of treating agitation using such film formulations. A Notice of Allowance is issued after the USPTO makes a determination that a patent should be granted from an application. The

patent, which is expected to be issued in the third quarter of 2020, will have a term that expires no earlier than 2039. After issuance, BioXcel plans to list the U.S. patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.

On June 11, 2020, BTI announced that the first patient had been enrolled in the Phase 1b/2 RELEASE trial of BXCL501 for the treatment of opioid withdrawal symptoms. The RELEASE trial is a multicenter, randomized, double-blind, placebo-controlled, ascending-dose Phase 1b/2 study designed to evaluate the safety, pharmacokinetics, tolerability and efficacy of BXCL501 in patients experiencing symptoms of opioid withdrawal. This study will enroll approximately 125 subjects with opioid use disorder who are physically dependent on opioids. During the 7-day treatment phase, BXCL501 will be evaluated in sequential, ascending dose cohorts of 30ug, 60ug, 90ug, 120ug, and 180ug, administered twice daily (BID), approximately 12 hours apart. The study will assess opioid withdrawal symptoms using both the Clinical Opiate Withdrawal Scale and Short Opiate Withdrawal Scale of Gossop over a 10-day period.

The information included in Item 2.02 of this Current Report on Form 8-K is incorporated by reference into this Item 8.01.

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. Forward-looking statements in this Form 8-K include but are not limited to statements regarding the timing and data from clinical development initiatives and trials for BXCL501, the potential commercialization of BXCL501 and BTI's corporate strategy and intellectual property portfolio. 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.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, without limitation, BTI'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 BXCL501 and BXCL701 and other product candidates; the failure of preliminary data from its clinical studies to predict final study results; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; 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, 2020, 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 its 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 BTI 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 BTI'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: July 27, 2020

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer