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 19, 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. ("we" or "our") had cash and cash equivalents totaling $32.4 million as of December 31, 2019.

Item 8.01 Other Events.

We are providing the following business update.

Recent Developments

BXCL501 Neuroscience Program

On July 22, 2019, we announced positive top-line results from the adaptive Phase 1b, randomized, double-blind, placebo-controlled, multi-center, U.S. trial, evaluating multiple doses of BXCL501 for acute treatment of agitation in 135 patients with schizophrenia. In the trial, a reduction in the Positive and Negative Syndrome Scale, Excitatory Component score, or the PEC Score, for agitation was observed with rapid calming without excessive sedation at two hours and at earlier time-points. The 80 mcg, 120 mcg and 180 mcg doses of BXCL501 showed reductions of PEC scores of -7.1, -9.2 and -10.8, respectively, compared to -4.5 for placebo at two hours. The results for these three doses were statistically significant in patients treated compared to placebo 80 mcg ($p=0.0152$), 120 mcg ($p=0.0003$), and 180 mcg ($p<0.0001$) with clinically meaningful, rapid and durable reductions in PEC score. We also observed clinically meaningful but not statistically significant reductions in PEC scores of -6.0 following 60 mcg at two hours ($p=0.1227$). We believe that these results suggest a predictable and dose-dependent response for BXCL501. In addition, results from secondary analyses showed statistically significant calming as measured by the ACES (Agitation-Calmness Evaluation Scale) at two hours compared to placebo following a single dose of 80 mcg ($p=0.0156$), 120 mcg ($P=0.0005$) and 180 mcg ($P<0.0001$). In this trial, BXCL501 was well tolerated with no serious or severe adverse events across the entire dose range.

On August 20, 2019, we announced that the U.S. Department of Defense's Congressionally Directed Medical Research Program awarded a planning grant as a part of its Alcohol and Substance Abuse Disorders Research Program related to the development of BXCL501. The grant is expected to support the development of a clinical study to evaluate the use of BXCL501 for the treatment of alcohol and substance use disorders, particularly related to post-traumatic stress disorder and traumatic brain injury.

On September 18, 2019, we announced plans to investigate the development of using wearable digital device technology such as the Apple Watch, with the goal of enhancing the prevention and treatment of agitation including, if approved, the administration of BXCL501 prior to the onset of agitation. We plan to conduct a feasibility study with potential applications in commercially available wearable digital devices to measure nervous and motor system activity relevant to both agitation and the mechanism of action of BXCL501. This study is expected be conducted in collaboration with both clinical investigators and a third-party digital solutions provider.

On December 30, 2019, we announced the initiation of our SERENITY (Sub-Lingual Dex in Agitation Associated With SchizophRENIa and Bipolar Disorder STudY) program, which consists of two Phase 3 trials of BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorder. Topline data from both of these Phase 3 trials are expected in mid-2020.

On January 7, 2020, we announced that the first patient had been enrolled in a Phase 1b/2 trial of BXCL501 for the acute treatment of agitation in patients with dementia. Topline data from this trial are expected in mid-2020.

On February 5, 2020, we announced FDA clearance of our investigational new drug application, or IND, for BXCL501 for the treatment of opioid withdrawal symptoms. We are preparing to initiate a Phase 1b/2 clinical trial.

On February 18, 2020, we announced the initiation of an investigator sponsored clinical trial designed to evaluate the safety and efficacy of BXCL501 and measure biomarkers associated with agitation in patients with schizophrenia and their response to treatment with BXCL501. The trial is designed to identify biomarkers, such as skin conductance response, heart rate variability, and blood pressure, that can potentially be used as an initial signal for treatment and expand the BXCL501 development program to evaluate new chronic disease indications.

Finally, we are continuing to evaluate development plans for BXCL501 as a potential treatment for acute agitation in hyperactive delirium and for chronic agitation, as well as developing a single-use intramuscular injection for severe agitation.

BXCL701 Immuno-Oncology Program

We are currently enrolling patients in the United States in a Phase 1b/2 clinical trial evaluating the double combination of BXCL701 and Keytruda® for the treatment of emergent neuroendocrine prostate cancer. Data as of January 30, 2020 from this open label trial of patient cohorts consisting of 400 mcg of BXCL701 in combination with Keytruda® and 600 mcg of BXCL701 in combination with Keytruda® showed on-target adverse events that we believe are consistent with cytokine activation at the highest once-daily dose tested. BXCL701 also showed preliminary pharmacokinetic results that were within expectations. Of the 6 patients dosed as of the data cutoff date, the majority of patients remained on treatment. One patient experienced acidosis with a fatal outcome that was determined by the investigator to be possibly related to BXCL701. We are currently enrolling patients in the 600 mcg cohort with a split dose and expect to complete dosing in the first quarter of 2020. Topline data from the Phase 1b portion of this trial are expected in the second half of 2020, prior to advancing to the Phase 2 efficacy portion of the trial.

In June 2019, we announced that our Clinical Trial Application was accepted by the U.K. Medicines and Healthcare products Regulatory Agency for the double combination trial of BXCL701 and Keytruda® in treatment-related neuroendocrine prostate cancer patients. We have activated two clinical sites in the U.K. and are planning to open a third clinical site, subject to approval from local U.K. authorities. This is the first step in our plan to expand our clinical trials globally.

In June 2019, we reported that the FDA had cleared the IND for the triple combination of BXCL701, bempegaldesleukin (produced by Nektar Therapeutics, Inc., or Nektar) and BAVENCIO® (avelumab, Merck KGaA, Darmstadt, Germany and Pfizer) in pancreatic cancer. We expect to initiate the trial in the second half of 2020, following a safety run-in trial of Avelumab and bempegaldesleuk to be conducted by Pfizer and Nektar and the outcome of their trial.

On September 4, 2019, we announced that the FDA granted Orphan Drug Designation for BXCL701 for the treatment of acute myeloid leukemia.

On December 11, 2019, we announced that the M.D. Anderson Cancer Center is planning to initiate an investigator-led Phase 2 trial evaluating the double combination of BXCL701 and Keytruda® in multiple solid tumors. M.D. Anderson has indicated that it expects to initiate this trial in the first half of 2020, with initial data anticipated in the second half of 2020.

Finally, we are continuing to explore additional indications for BXCL701 with synergistic combinations.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business, including by seeking, maintaining, and defending patent rights. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in our field.

As of February 17, 2020, we have filed applications in the core patent family protecting BXCL501 in the United States, Taiwan and as a pending patent cooperation treaty, or PCT, application. We expect that patents issuing from these applications, if any, will expire no earlier than 2039. We have also filed applications in several additional patent families that are relevant to BXCL501. We have filed applications pending in the United States, Europe and Japan directed to methods of treating insomnia using sublingual Dex. We expect that patents issuing from these applications, if any, will expire no earlier than 2035. We also have filed patent applications in fifteen jurisdictions, including the United States, Europe, Japan and China, directed to methods of treating agitation. We expect that patents issuing from these applications, if any, will expire no earlier than 2037. We also have filed a PCT application directed to intravenous administration of Dex. We expect that patents issuing from this application, if any, will expire no earlier than 2039. In addition to these, we have eight provisional patent applications directed to various aspects of the BXCL501 program. We expect that patents issuing from these applications, if any, will expire between 2039 and 2040. Finally, we have a design patent application, which, if it issues, would expire fifteen years from the date of grant.

We have multiple patent families filed to protect our BXCL701 program, including our core patent family directed to methods of using BXCL701 with immune checkpoint inhibitors, which is filed in the United States and seventeen other countries. Patents issuing from that family, if any, should expire no earlier than 2036. We have a PCT application directed to combination therapies using BXCL701 with immune checkpoint inhibitors and approaches for modifying T-cell activity. We expect patents issuing from this family, if any, to expire no earlier than 2038. Additional PCT and ex-US applications are directed to administering BXCL701 in combinations with various other molecules and dosing regimens. We expect that patents issuing from these applications, if any, will expire no earlier than 2039. Finally, we have four provisional applications directed to various aspects of the BXCL701 program. Patents issuing from those applications, if any, are expected to expire between 2039 and 2041 at the earliest.

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 includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this Current Report on Form 8-K include but are not limited to the timing of trials involving BXCL501 and BXCL507; the timing of data from such trials and the expiration of patents involving these product candidates. 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; 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; 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, 2019, 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 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 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 our 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 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: February 19, 2020

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer