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)
December 19, 2018

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)

(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))

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.

On December 19, 2018, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing that the first six subjects have been dosed in the Company's Phase 1 pharmacokinetic (bioavailability) and safety study of BXCL501, a proprietary sublingual thin-film formulation of dexmedetomidine. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 19, 2018

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: December 20, 2018

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Doses First Subjects in Pharmacokinetic (Bioavailability) and Safety Study of BXCL501 for the Acute Treatment of Agitation

Data read-out expected in 1H 19

Results expected to support dose selection for anticipated registration trials in 2019

NEW HAVEN, Conn., Dec. 19, 2018 — BioXcel Therapeutics, Inc. ("BTI" or "Company") (Nasdaq: BTAI), today announced that the first six subjects have been dosed in the Company's Phase 1 pharmacokinetic (bioavailability) and safety study of BXCL501, a proprietary sublingual thin-film formulation of dexmedetomidine (Dex). BTI is a clinical-stage biopharmaceutical development company utilizing novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and immuno-oncology.

The IND-opening Phase 1 study is a placebo-controlled, single dose, dose-escalation study of BXCL501 that is expected to enroll up to 60 healthy adult volunteers across various dosing groups. The primary endpoints are pharmacokinetics and safety, with secondary endpoints including assessment of pharmacodynamics (PD) and the relationship between BXCL501 concentrations and PD endpoints. The Company expects to report top-line data from the study in the first half of 2019 that it anticipates will provide a path for BTI to launch the anticipated registration studies.

Dr. Vincent J. O'Neill, Chief Medical Officer of BTI commented, "Acute agitation affects millions of patients across a variety of neuropsychiatric indications. Previously announced proof of concept data from the trial in schizophrenia patients with IV Dex suggest that BXCL501 could be a viable treatment for acute agitation that overcomes the many issues associated with existing therapies. This study will help inform dose selection for our anticipated registration trial, which we plan to initiate in 2019 and we look forward to the results, which we expect in the first half of 2019."

Dr. Frank Yocca, Chief Scientific Officer of BTI added, "The acute treatment of agitation represents a major unmet medical need and a significant burden on the healthcare system. BXCL 501 directly targets a causal agitation mechanism independent of underlying disease conditions and its proprietary sublingual thin-film formulation delivers a potentially efficacious dose of drug, while providing a number of advantages over existing therapies for acute agitation, which are invasive, difficult to administer and have serious potential side effects."

BTI continues to explore expanding the range of target indications for BXCL501 beyond its current focus areas of acute treatment of agitation in schizophrenia, bipolar disorder and dementia. Treatment of agitation remains a significant global healthcare challenge in patients with drug and alcohol withdrawal, delirium and post-traumatic stress disorder, as the currently available treatment options are suboptimal, invasive, difficult to administer and often pose safety issues.

About BXCL501:

BXCL501 is a first in class, proprietary sublingual film of dexmedetomidine, a selective alpha 2a receptor agonist intended for the treatment of acute agitation. BTI believes that BXCL501 directly targets a causal agitation mechanism and has demonstrated anti-agitation effects in preclinical and clinical studies. It has a well-established regulatory and reimbursement path for the acute treatment of agitation in schizophrenia and bipolar disorder, as demonstrated by Adasuve, a drug previously-approved by the FDA.

About Treatment of Agitation:

Agitation, including the acute treatment of agitation, remains a growing global healthcare burden. The Company estimates the total direct financial cost of all aspects of care for agitation in Alzheimer's disease to be approximately $40 billion per year. The Company believes approximately 5.0 million patients with Alzheimer's

disease, schizophrenia and bipolar disorder experience agitation in the U.S. Approximately 1.1 million of these patients experience mild to moderate agitation and represent a potential patient population for treatment with BXCL501.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and immuno-oncology. BTI'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. BTI's two most advanced clinical development programs are BXCL501, a sublingual thin film formulation designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer. For more information, please visit www.bioxceltherapeutics.com

Forward-Looking Statements:

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, statements that relate to the advancement and development of BXCL501 and BXCL701, the commencement of clinical trials, the availability of data from clinical trials and other information that is not historical information. When used herein, words such as "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 BioXcel's current expectations and various assumptions. BioXcel believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. BioXcel 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, market conditions and the factors described under the caption "Risk Factors" in BioXcel's Form 10Q for the period ending September 30, 2018, and BioXcel's other filings made with the Securities and Exchange Commission. Consequently, forward-looking statements should be regarded solely as BioXcel's current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. BioXcel cannot guarantee future results, events, levels of activity, performance or achievements. BioXcel does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.

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