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)
November 14, 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 x

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. x

Item 8.01 Other Events.

On November 14, 2018, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing positive results from a Phase 1b study evaluating intravenously administered dexmedetomidine for acute treatment of agitation in patients suffering from schizophrenia. 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 November 14, 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: November 14, 2018

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Positive Results from Study in Agitated Schizophrenia Patients Supporting BXCL501 Clinical Development

Primary endpoint met, clinical benefit observed in 9 of 10 patients treated with intravenously (IV)-dosed Dexmedetomidine(Dex); no meaningful responses observed in placebo arm

IV Dex well tolerated in treatment arm

New Haven, Conn., November 14, 2018 — BioXcel Therapeutics, Inc. ("BTI") (Nasdaq: BTAI), a clinical stage biopharmaceutical development company utilizing novel artificial intelligence to identify the next wave of medicines across neuroscience and immuno-oncology, today announced positive results from a Phase 1b study evaluating intravenously (IV) administered dexmedetomidine (Dex) for acute treatment of agitation in patients suffering from schizophrenia. The trial met its primary endpoint by identifying a safe dose of IV Dex that produced a mild arousable sedation, defined by a RASS(1) (Richmond Agitation Sedation Scale) score of -1. Data from this study will guide BTI in selecting the optimal dose for BXCL501, a sublingual thin film formulation of Dex, for the acute treatment of agitation.

The study enrolled a total of fourteen (14) patients. Ten (10) patients in the treatment arm received IV Dex therapy, while four (4) patients received placebo. Dose escalation was performed by infusing 0.2 to 0.6 mcg/kg/hr of the IV formulation of Dex over a period of 30 minutes. The dose range in this study was consistent with the range used in a previous study conducted in healthy volunteers.

The study demonstrated that 9 out of 10 patients in the treatment arm achieved a RASS score of -1, while no patients in the placebo arm experienced meaningful sedation. Additionally, the drug was well tolerated without any clinically adverse effects on blood pressure and/or heart rate. As a secondary endpoint, 9 out of 10 patients in the treatment arm had agitation reduced to a minimum (as measured by a PEC(2) score of 7 or below) in contrast with 0 out of 4 of the placebo patients.

Vincent O'Neill, MD, Chief Medical Officer of BTI, commented, "We were pleased with the outcome of this trial of IV Dex in schizophrenic patients and the support it offers for the clinical development of BXCL501. The study met its primary endpoint and demonstrated that the mild sedative effects of the IV formulation of Dex lasted for 1.5 to 2 hours, a clinically relevant duration, in 9 out of the 10 patients who received drug. IV Dex was also well tolerated in patients, the majority of whom were receiving anti-psychotic drugs prior to being administered the IV Dex dose. The findings from this study are highly encouraging and demonstrate the potential of our BXCL501 as a fast acting and easy to administer therapy

for acute treatment of agitation. We look forward to the results from the parallel study evaluating IV Dex in patients with senile dementia of Alzheimer's type (SDAT), expected prior to year-end."

Sheldon Preskorn, MD, Professor in the Department of Psychiatry at the University of Kansas School of Medicine-Wichita and a member of the Company's Clinical Advisory Board commented, "This study demonstrates that IV Dex produces a rapid calming effect via a novel mechanism of action that has the potential to safely and rapidly reduce agitation in patients with schizophrenia. Although agitation is a commonly encountered and important phenomenon in clinical practice, there are currently few treatment options approved for the acute treatment of agitation."

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(1) RASS is a 10-point (+4 "combative" to -5 "unarousable") medical scale used to measure the agitation or sedation level of a patient.
(2) PEC (Positive and Negative Symptom Scale - Excitatory Component) is a five item scale that measures symptoms of agitation with each item rated from 1 (Absent) to 7 (Extreme).

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence 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.

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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