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 27, 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.)

780 East Main Street
Branford, CT 06405
(Address of principal executive offices, including ZIP code)

(203) 643-8060
(Registrant's telephone number, including area code)

Not Applicable
(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 June 27, 2018, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing positive data from its Phase 1b study evaluating intravenous administration of dexmedetomidine, or Dex. Data from this study will aid in establishing the optimal dose for BXCL501, a sublingual formulation of Dex, for the acute treatment of agitation. 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 June 27, 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: June 27, 2018

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Positive Results from Phase 1b Trial of Intravenously-dosed Dexmedetomidine Supporting BXCL501 Development

Optimal exposure levels for developing BXCL501 sublingual thin film identified

Results support clinical evaluation of dexmedetomidine in acute treatment of agitation resulting from neuropsychiatric disorders and dementia

BRANFORD, Conn., June 27, 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 data from its Phase 1b study evaluating intravenous (IV) administration of dexmedetomidine (Dex). Data from this study will aid in establishing the optimal dose for BXCL501, a sublingual formulation of Dex, for the acute treatment of agitation.

Sheldon Preskorn, MD, a leading Psychiatric Drug Development Expert and BTI's Neuroscience Clinical Advisor, commented, "The development of a medication that treats agitation without the various safety concerns of existing options is a large unmet medical need — a topic addressed at a symposium(1) conducted on June 14th in New York City by the New York Academy of Sciences. The current Phase 1b study was designed to evaluate the safety and establish an optimal exposure range. This information will be used to determine the ideal dosing strategy for the continued clinical development of BXCL501."

BTI completed the first part of its Phase 1b, randomized, placebo-controlled, dose ranging, single-center study of the IV formation of Dex in healthy middle-aged and elderly participants. The study enrolled 16 healthy volunteers aged 55-75. The primary endpoint of the study was the dose and drug exposure levels required to produce mild sedation, which can serve as a surrogate endpoint for treating agitation using the Richmond Agitation- Sedation Scale (RASS)(2) score. The goal of the study was to achieve mild sedation without any clinically meaningful cardiovascular side effects. In this study:

- Dose escalation was performed by infusing 0.1 mcg to 0.6 mcg of the IV formulation of Dex over 30 min.
- An optimal starting dose of 0.3 mcg was determined in cohort 1 and subsequently used in cohort 2.
- The IV formulation of Dex was found to achieve mild sedation or a RASS score of -1 in patients at a Dex exposure level without producing any clinically meaningful effects on blood pressure and/or heart rate.
- This effect was evident in 11/12 subjects on the IV formulation of Dex and occurred within 30 minutes of starting the dose which produced the desired effect. In contrast, a mild sedating effect was seen in only 1 out of 4 individuals on placebo. The mild sedative effects of the IV formulation of Dex persisted for 1.5-2 hours, a clinically relevant duration.
- Inter-individual variability of the IV formulation of Dex was limited by dose titration.
- The IV formulation of Dex was well tolerated.

(1) Psychiatric Symptoms in Alzheimer's Disease and Dementia symposium
(2) RASS is a 10-point (+4 "combative" to -5 "unarousable") medical scale used to measure the agitation or sedation level of a patient.

"Treatment of agitation remains a significant global healthcare challenge in patients with various neuropsychiatric disorders and dementia, as the currently available treatment options are suboptimal, invasive, difficult to administer and often pose safety issues especially in the elderly. The positive data from this Phase 1b study of the IV formulation of Dex represents an important step forward in the clinical development of BXCL501," said Dr. Vincent J. O'Neill, Chief Medical Officer of BTI. "These results clearly demonstrate doses and exposure levels of the IV formulation of Dex that have calming effects in healthy subjects without clinically meaningful changes in blood pressure or heart rate. With these findings in hand, we plan to evaluate the selected dose and exposure levels identified in this ongoing Phase 1b study in patients with senile dementia of the Alzheimer type (SDAT)."

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 prospectus dated March 7, 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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