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 4, 2019

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 February 4, 2019, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing proof-of-concept data from its Phase 1b study of intravenously-administered dexmedetomidine in patients suffering from opioid withdrawal symptoms. 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 February 4, 2019

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 4, 2019

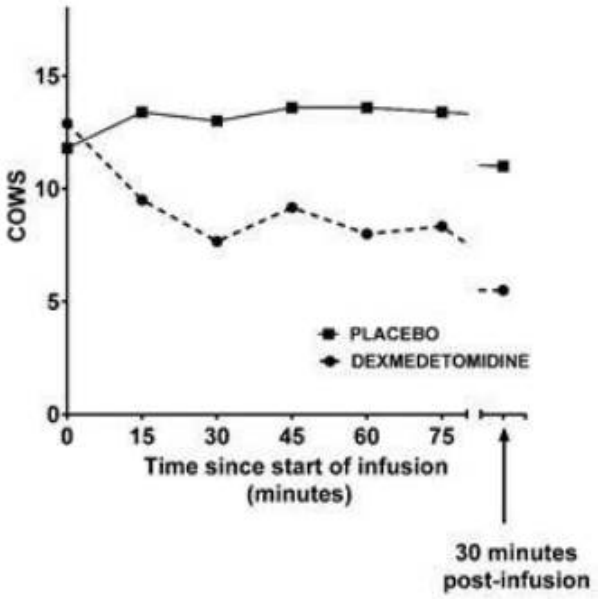
BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

February 4, 2019

BioXcel Therapeutics Expands Indication for Lead Neuroscience Asset, BXCL501, to Treat Symptoms Associated with Opioid Drug Withdrawal

Clinical benefit observed in 10 of 10 patients; Human proof-of-concept established



Clinical opioid withdrawal symptoms during an escalating infusion of Dex (10 subjects) vs. placebo (5 subjects). Once symptoms reduced by ≥ 50% the infusion was stopped and symptoms measured 30 minutes later. For subjects who did not achieve a reduction, after 3 hours the infusion was stopped and symptoms measured 30 minutes later.

Provides further evidence of BXCL501's mechanism of action

Expands clinical advisory board with four additional industry leaders to guide on global development and market expansion of BXCL501

NEW HAVEN, Conn., Feb. 04, 2019 (GLOBE NEWSWIRE) — BioXcel Therapeutics, Inc. ("BTI" or "Company") (Nasdaq: BTAI), today announced proof-of-concept data from its Phase 1b study of intravenously-administered dexmedetomidine (IV Dex) in patients suffering from opioid withdrawal symptoms. The positive data from this Phase 1b trial provides evidence to expand the potential market for BXCL501, a first in class proprietary sublingual film of Dex, beyond its current focus for acute treatment of agitation in

neuropsychiatric indications. 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 study further confirms that BXCL501's selective alpha-2a adrenergic receptor mechanism has potential application in opioid withdrawal symptoms, in addition to the acute treatment of agitation in schizophrenia, bipolar disorder and dementia. Opioid addiction is difficult to overcome largely because of the severe symptoms associated with withdrawal, an area in need of more effective non-opioid treatment options.

BTI conducted the clinical study in a total of 15 patients with opioid dependence. Ten subjects were enrolled in the treatment arm while five subjects were enrolled in the placebo arm. Symptoms of opioid withdrawal were evaluated using the Clinical Opioid Withdrawal Scale (COWS)(1), an 11-item scale that measures a constellation of withdrawal symptoms experienced after abstaining from opioid use. All ten subjects receiving IV Dex responded to treatment, while there were no responders in the placebo arm. Results from this study demonstrated that IV Dex effectively mitigated the physiological symptoms of opioid withdrawal. These encouraging results support further expansion of BXCL501 for the treatment of withdrawal symptoms associated with opioid abuse. Additionally, previously published studies support the potential of Dex as an adjunctive treatment for symptoms of alcohol withdrawal(2).

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/5cf6d3d4-b46f-46c2-8124-52cec37a7d2c

Dr. Frank D. Yocca, Chief Scientific Officer noted, "We believe that developing new, non- opioid treatments for opioid withdrawal symptoms represents a major step towards combating this growing healthcare crisis. We believe that the current regulatory environment is conducive to development of novel therapeutic options for patients battling the symptoms of opioid withdrawal. Dex exerts its effects by selectively blocking alpha-2a adrenergic receptors on neurons that originate from the locus coeruleus in the brainstem. Opioid withdrawal is characterized by physiological activation of this system. This study demonstrates BXCL501's potential to combat agitation as well as other physiological symptoms of opioid withdrawal. We believe BXCL 501's potency, ease of administration and selective mechanism of action in reducing hyper-arousal have the potential to provide therapeutic benefit to patients across a broad range of indications."

Dr. Robert Risinger, MD Vice President, Clinical Development of BTI added, "Opioid withdrawal symptoms are challenging medical conditions that have reached epidemic proportions and are in need of additional effective therapies. We are very excited by the efficacy IV Dex demonstrated in treating the symptoms of opioid withdrawal. We believe that BXCL501 offers distinct advantages due its intrinsic potency combined with ease of use associated with sublingual film. Based on the strong clinical results from our study and validation of its mechanism of action, we are currently exploring development plans for

BXCL501 in this large, underserved indication with limited treatment options."

BXCL501 Program Update:

BTI is currently dosing patients in a Phase 1 placebo-controlled, single dose, dose- escalation study of BXCL501. The study is expected to enroll up to 60 healthy adult volunteers across various dose 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 this study in the first half of 2019.

BTI continues to explore a 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 and BXCL501 may prove to be useful as well in patients suffering with opioid 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.

BTI Clinical Advisory Board Update:

Additionally, the Company expanded its Neuroscience Clinical Advisory Board (CAB) to eight members with the appointment of Dr. John Krystal, Dr. Maurizio Fava, Dr. Thomas Laughren and Dr. Thomas Kosten. The new members of the CAB along with its existing members will provide valuable counsel on global development of the Company's lead neuroscience asset, BXCL501, in a broad range of indications as well as other emerging neuroscience programs.

Dr. Krystal is the Robert L. McNeil, Jr. Professor of Translational Research and Professor of Psychiatry, Psychology and of Neuroscience; Chair of Department of Psychiatry and Chief of Psychiatry at the Yale-New Haven Hospital. He is a leading expert in the areas of alcoholism, post-traumatic stress disorder, schizophrenia, and depression and has been crucial in the discovery of the rapid antidepressant effects of ketamine in depressed patients.

Dr. Fava serves as the Director of Division of Clinical Research of the MGH Research Institute, Executive Vice Chair of the MGH Department of Psychiatry and the Executive Director of the MGH Clinical Trials Network & Institute (CTNI) at the MGH Research Institute. Dr. Fava is a world leader in the field of depression. He has served as the principal or co-principal investigator for numerous clinical studies, most notably as the co- principal investigator of STAR*D, the largest research study ever conducted in the area of depression, and of the RAPID Network, the NIMH-funded series of studies of novel, rapidly-acting antidepressant therapies.

Dr. Laughren is the Director of Regulatory Affairs, MGH Clinical Trials Network and Institute and is also a consultant in psychiatric drug development in several other settings as well. Most recently he retired as the Division Director for the Division of Psychiatry Products, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration ("FDA") where he oversaw the review of all psychiatric drug development

activities conducted under INDs and the review of all NDAs and supplements for new psychiatric drug claims.

Dr. Kosten is the JH Waggoner Chair and Professor of Psychiatry, Pharmacology, Immunology and Neuroscience, and founding Co-director of the Dan L. Duncan Institute for Clinical and Translational Research (ICTR) at Baylor College of Medicine. His pharmacotherapy research activities include a cocaine vaccine, disulfiram for cocaine dependence, vasodilators for cocaine-induced cerebral perfusion defects and buprenorphine for opioid dependence. He also has advanced the understanding of opioid and cocaine dependence mechanisms and treatment using SPECT and functional MRI neuroimaging.

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(1) The Clinical Opiate Withdrawal Scale is an 11 item scale whereby a clinician assigns a numerical score for each characteristic sign and symptom of opiate withdrawal. The sum total score is used to grade and track the severity of physiological withdrawal from opioids.

(2) *The Journal of Addictions Nursing & Volume 28 & Number 4, 188Y195 & Copyright B 2017 International Nurses Society on Addictions* Addition of Dexmedetomidine : Adjunctive Therapy to Benzodiazepine Use in Alcohol Withdrawal Syndrome Tarenne A. Ferenchak, BA, BSN, MSN, RN

About BXCL501:

BXCL501 is a first in class, sublingual film of dexmedetomidine, a selective alpha2a adrenergic receptor agonist for the acute treatment of agitation. BTI believes that BXCL501 directly targets a causal agitation mechanism and has demonstrated anti- agitation effects in preclinical and clinical studies in schizophrenia, bipolar disorder, and dementia. There is a well-established regulatory and reimbursement path in schizophrenia and bipolar disorder, as demonstrated by a previously-approved drug, Adasuve. BXCL501 has been granted Fast Track designation by the FDA.

About Opioid Drug Withdrawal:

According to the Centers for Disease Control and Prevention (CDC), the misuse of and addiction to opioids is a serious national crisis. They estimate the total “economic burden” of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement. Between 1999-2017, almost 400,000 people died from an overdose involving an opioid, with greater than 47,000 deaths occurring in 2017 alone. Opioid withdrawal is a condition characterized by symptoms such as anxiety, agitation, sleep problems, muscle aches, runny nose, sweating, nausea, vomiting, diarrhea and drug craving — that occur after stopping or reducing the use of opioids in anyone with physical dependence on opioids.

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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