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)
January 3, 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 7.01 Regulation FD Disclosure.

On January 3, 2019, BioXcel Therapeutics, Inc. (the "Company") held an investor conference call and discussed the results of the study described in Item 8.01 below and the Company's BXCL501 program. In connection with the investor call, the Company prepared presentation materials ("the Presentation Materials"), a copy of which are furnished as Exhibit 99.1 to this current report on Form 8-K. The call will be available via a live, listen-only webcast at http://public.viavid.com/index.php?id=132677 and archived for 30 days.

The information contained in the Presentation Materials is summary information that should be considered within the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company may make by press release or otherwise from time to time. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so.

The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K is furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in any such filing.

Item 8.01 Other Events.

On January 3, 2019, the Company issued a press release announcing proof-of-concept data from its Phase 1 study of intravenous dexmedetomidine for acute treatment of agitation in patients with Senile Dementia of the Alzheimer's Type (SDAT). A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation, dated January 3, 2019
99.2	Press Release, dated January 3, 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: January 3, 2019

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1


bioxcel
therapeutics
(NASDAQ: BTAI)
BXCL501: An Acute Treatment for Agitation
January 03, 2019
BioXcel Therapeutics, 555 Long Wharf Drive, New Haven, CT 06511 | www.bioxceltherapeutics.com

Agenda

01 **BXCL501 PROGRAM OVERVIEW**

02 **CLINICAL TRIALS RESULTS WITH IV DEXMEDETOMIDINE**
ALZHEIMER'S | SCHIZOPHRENIA

03 **BXCL501 DEVELOPMENT PLAN IN 2019**

04 **SUMMARY**

ATTENDEES

- ✓ **Vimal Mehta,** *CEO & Member of Board*
- ✓ **Vincent O'Neill,** *Chief Medical Officer*
- ✓ **Frank Yocca,** *Chief Scientific Officer*
- ✓ **Robert Risinger,** *VP, Clinical Development*
- ✓ **Chetan Lathia,** *SVP & Head, Translational Medicine*
- ✓ **Sheldon Preskorn,** *Member, Clinical Advisory Board*

BXCL501: Sublingual Thin Film Dexmedetomidine (Dex) for Acute Treatment of Agitation

Rapid clinical development and regulatory approval path (505(b)(2))

Agitation: A **growing global healthcare issue ($40B+)**

Safer, non-invasive anti-agitation treatment needed

Current therapies sub-optimal:

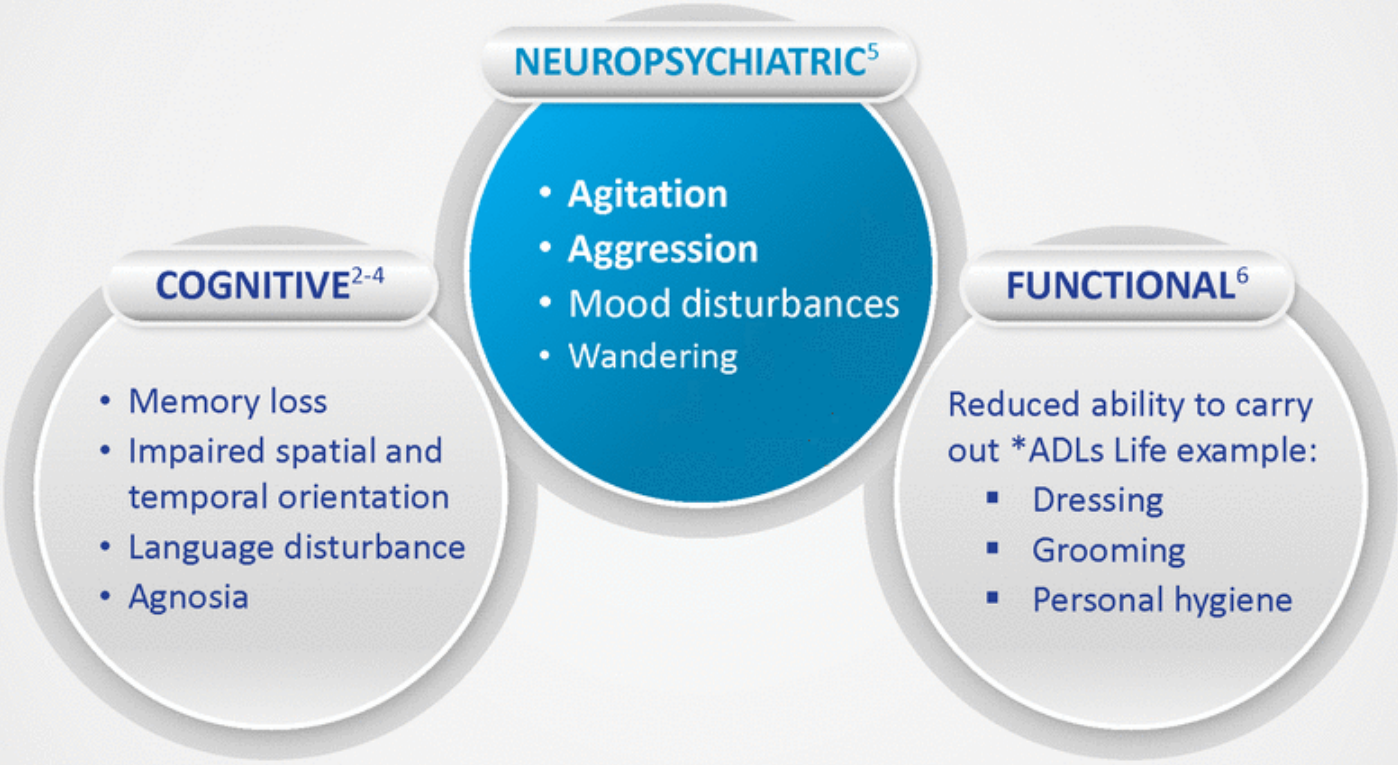
- ✓ **Dementia**: Antipsychotic drugs (black-box warning) for elderly
- ✓ **Psychiatric**: Invasive with severe side effects

BXCL501: An **innovative approach**

- ✓ Novel mechanism of action (MoA) targets a causal agitation pathway
- ✓ Non-Invasive, easy to administer **sublingual film** with **rapid onset of action**

Dementia: Symptoms of Alzheimer's Disease

Nearly half of the Alzheimer's patients have Agitation symptoms every month[1]



*ADL= Activity of daily living

1. Ryu SH, Katona C, Rive B, Livingston G, LASER-AD study;2005; 2.Joubert et al. In: Gauthier (ed);2007
3. Rainville et al. In: Gauthier (ed);2007; 4. Alzheimer's Association, Alzheimer's Dement 2016;12(4): 459-509;
5. Gelinas et al. In: Gauthier (ed);2007; 6.Teng & Cummings. In: Gauthier (ed);2007

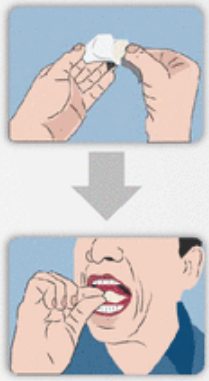
BXCL501: Sublingual Thin Film Formulation of Dexmedetomidine (Dex)

Dex exerts calming effect at low exposures providing a broad therapeutic index

Ideal Pharmaceutical Properties for a Non-invasive Sublingual Film Formulation

Film **manufacturing completed**:

- **Multiple dose strengths** ranging from **10µg to 60µg** for clinical studies
- **Immediate release** film with **muco-adhesion** properties
- **Proprietary technology** delivers **low dose ranges**



The Right Pharmacology and Safety Profile (Precedex® – IV Dex)

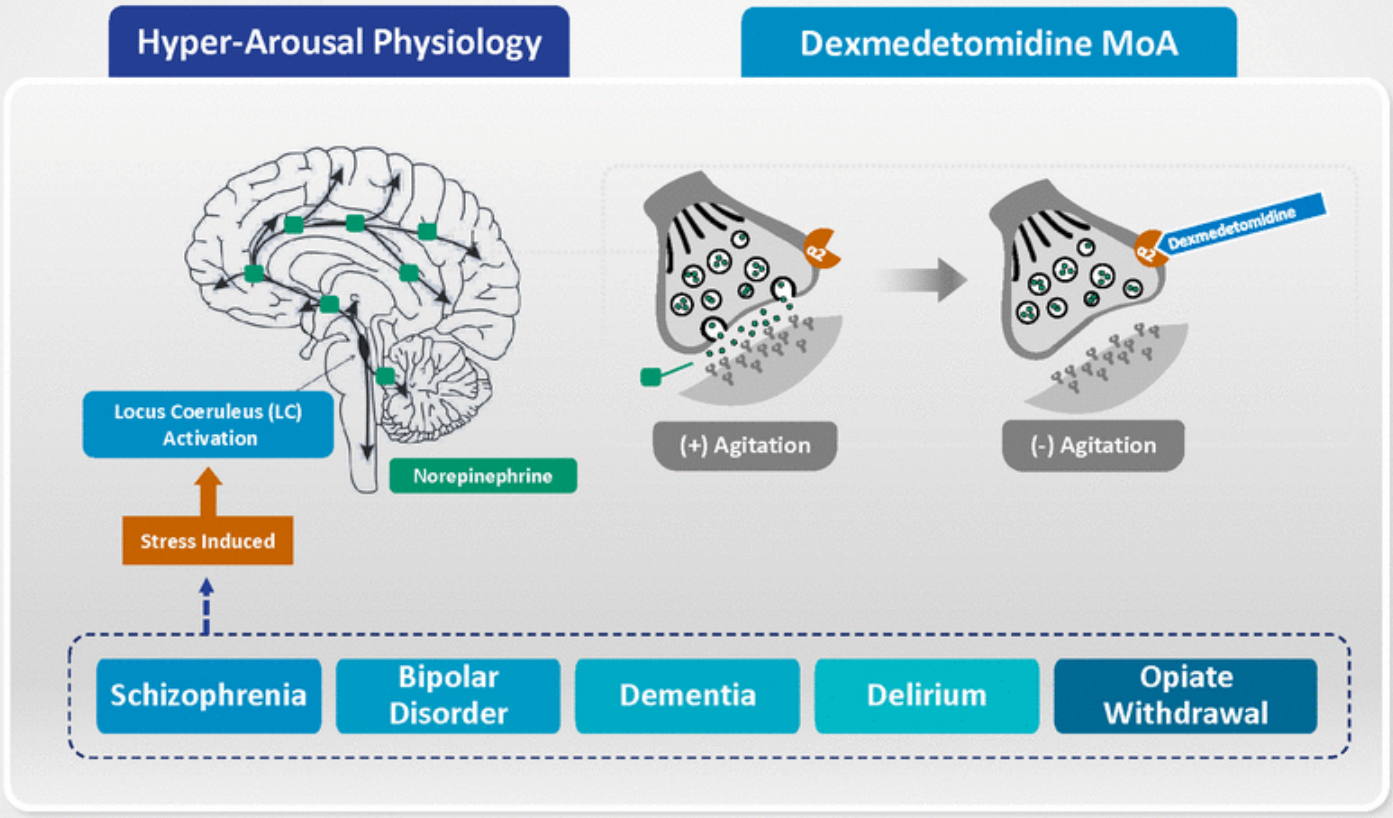
- Prescribed to **8M+ patients**
- Studied in **120 clinical trials**
- **Wide therapeutic index**

For Sedation in ICU Setting

Loading Dose	Maintenance Dose	Tolerable Dose
0.5µg/kg	*1.6µg/kg*	*>5µg/kg*

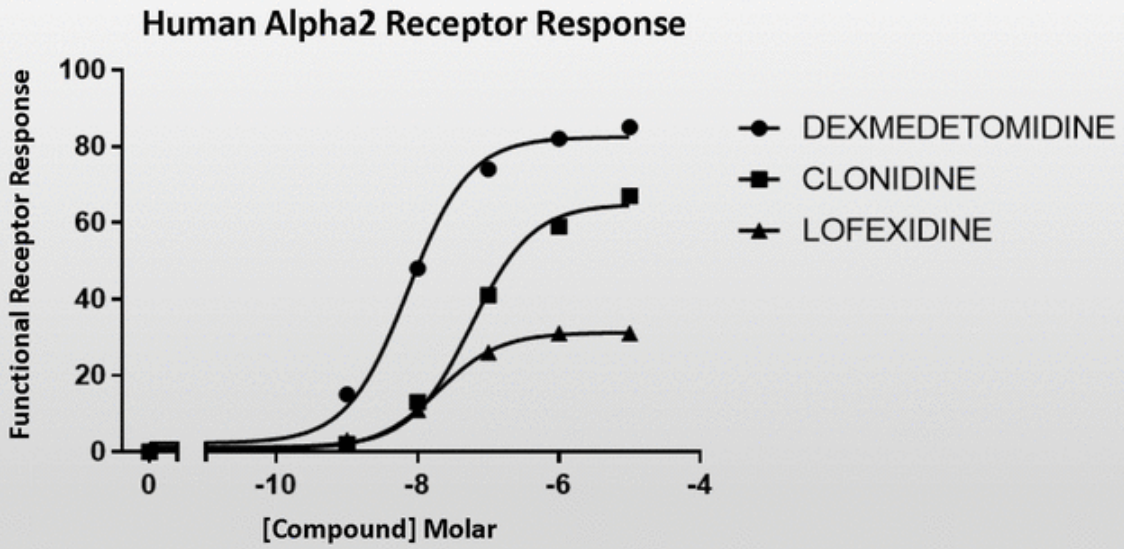
Dexmedetomidine Mechanism of Action

Reduction of hyper-arousal from overactive locus coeruleus neurons in response to stress



Dexmedetomidine: High Potency and Intrinsic Activity at Alpha2 Receptors

Data generated using transfected human Alpha2 receptor

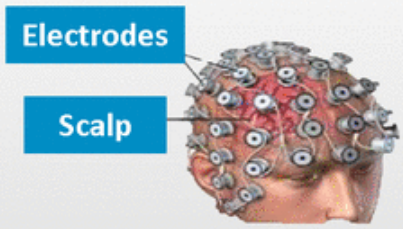


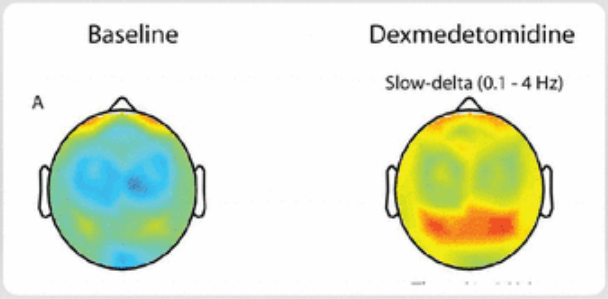
Dexmedetomidine: Pharmacology may translate into greater clinical efficacy

Human Biology Studies for BXCL501

Differentiate central nervous system (CNS) from peripheral effects

EEG Measurements



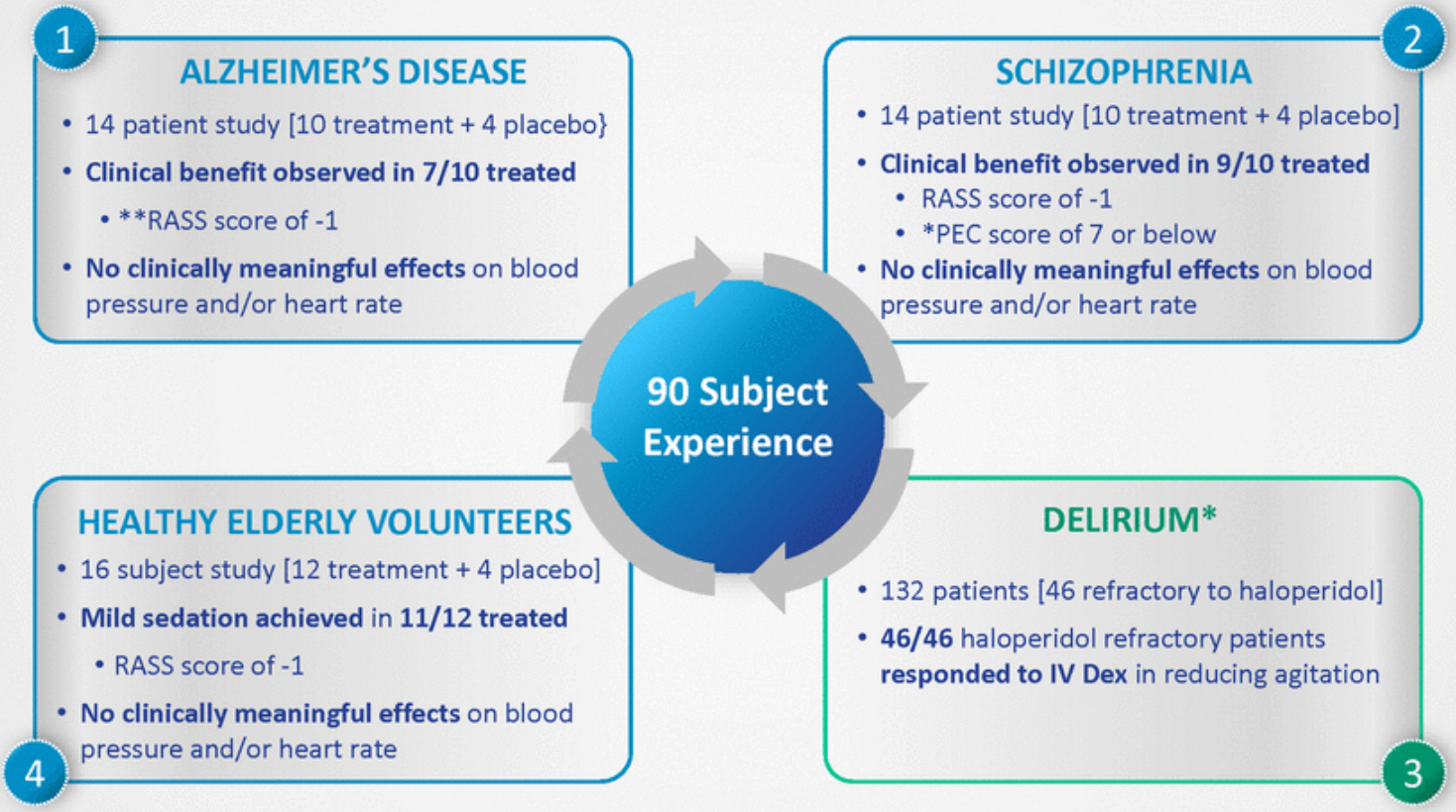


- Dex elicits a characteristic change in electroencephalographs (EEG)
- Plan to use EEG to demonstrate CNS activity that determines therapeutic window
  - Lowest dose with CNS activity
  - Highest dose without excessive drowsiness
- Determine onset of CNS effect and time course of recovery in agitated patients

Akeju O, Kim S-E, Vazquez R, Rhee J, Pavone KJ, Hobbs LE, et al. (2016) Spatiotemporal Dynamics of Dexmedetomidine-Induced Electroencephalogram Oscillations. PLoS ONE 11 (10): e0163431. doi:10.1371/journal. pone.0163431

IV Dex: Positive Human Proof of Concept in Treating Agitation from Alzheimer's Disease, Schizophrenia and Delirium

IV Dex data from 90 subjects: healthy volunteers and three disease pathologies



** *Richmond Agitation Sedation Scale*

* *Positive and Negative Symptom Scale-Excitatory Component*

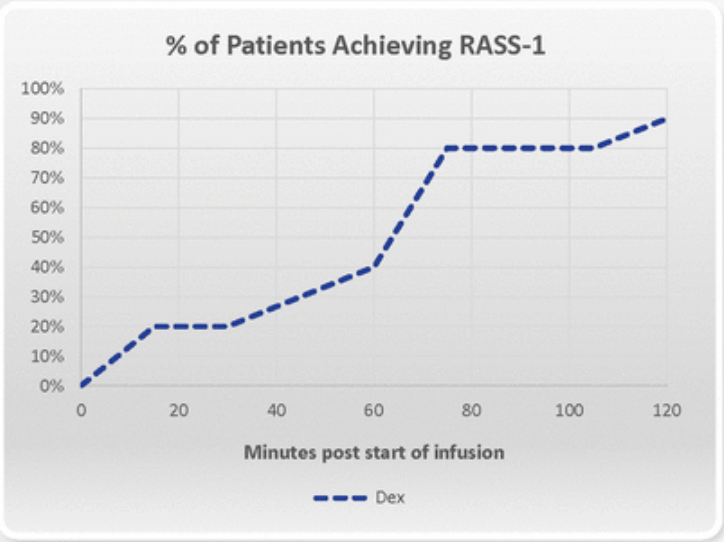
Carrasco et.al., Critical Care Medicine: July 2016, Vol 44, Issue 7, pp. 1295-1309

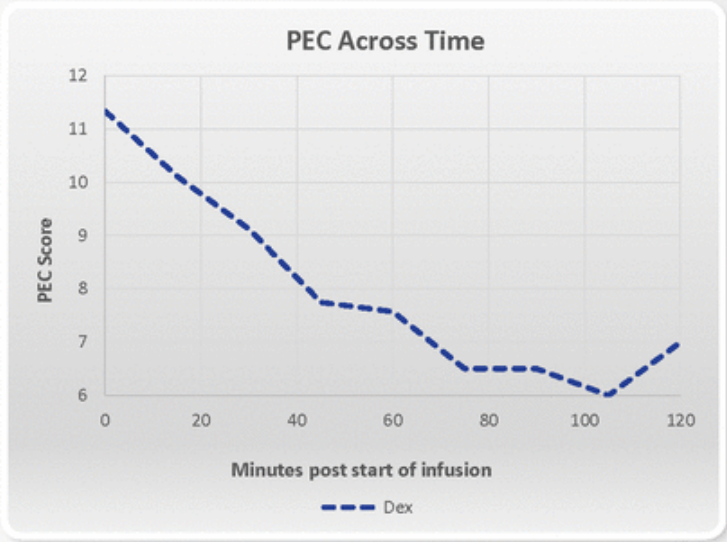
Human Proof of Concept 1: IV Dex Reduces Agitation in Schizophrenia Patients

Study results announced Nov 2018: primary endpoint met

Study Design

- Randomized, placebo-controlled dose-ranging study
- 14 patients [10 treatment + 4 placebo]
- Primary endpoint: RASS of -1
- Secondary endpoint: PEC score of 7 or below





9/10 patients achieved RASS score of -1

9/10 patients achieved PEC score of 7 or below

No clinically relevant cardiovascular changes

Early PEC reduction before drowsiness

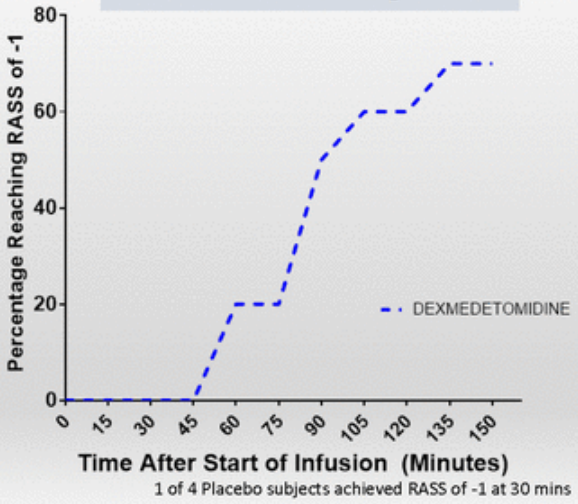
Human Proof of Concept 2: IV Dex Reduces Agitation in Alzheimer's Patients

Study results announced Jan 2019: primary endpoint met

Study Design

- Randomized, placebo-controlled individual dose-ranging study
- Infusion initiated at a low rate and increased by 0.1 mcg/kg/h
- 14 patients [10 treatment + 4 placebo]
- Primary endpoint: Optimal dose to achieve RASS of -1

% of Patients achieving RASS -1



1 of 4 Placebo subjects achieved RASS of -1 at 30 mins

Pharmacokinetics (PK) and Clinical Effect

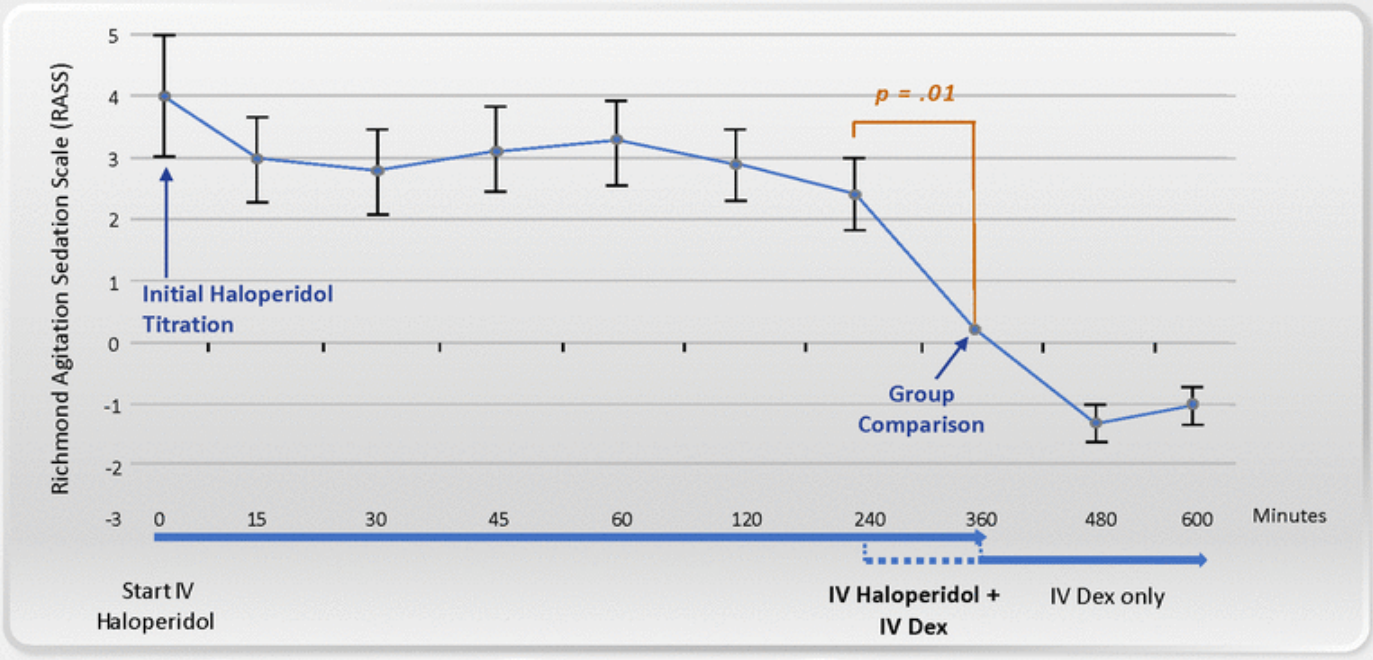
- **Pharmacokinetic/Pharmacodynamic (PK/PD)** observed with IV Dex concentrations (pg/mL)
- **Primary endpoint (RASS -1)** achieved at a fraction of dose required for surgical sedation

✓ **Identified a dose range for optimizing film (BXCL501)**

- 7/10 Patients Achieved RASS score of -1
- No Adverse Events (AE), well-tolerated
- No clinically meaningful cardiovascular effects
- PK consistent with prior healthy elderly trial

Human Proof of Concept 3: IV Dex Reduces Agitation in Haloperidol-Refractory Delirium

Elderly hyperactive delirium patients refractory to haloperidol are difficult to treat



46/46 haloperidol refractory patients calmed by IV Dex

IV Dex achieved greater time in satisfactory sedation

No respiratory or Heart Conduction disturbances

BXCL501 MoA shown to treat agitated delirium in elderly

* *Carrasco et.al., Critical Care Medicine: July 2016, Vol 44, Issue 7, pp. 1295-1309*

Sublingual Film (BXCL501) Pharmacokinetic and Safety Study

IND-opening study

BXCL501-101 Sublingual Pharmacokinetic, Safety and Tolerability Study

- Placebo-controlled, single ascending dose, pharmacokinetic (PK) study, safety & tolerability of BXCL501 (sublingual film) in healthy adult volunteers ages 18-65
- Primary objective
  - Determine PK, safety and tolerability of various film strengths
- Dosing initiated December 2018
- Accrual continues with periodic review between dose escalation
- Expect dosing completion 1Q2019

BXCL501 Integrated Clinical Development Plan

Acute agitation studies: short with easily measurable clinical endpoints

[IND]
2018

2019

2020
[First NDA Submission]

Sublingual Thin Film

PK and Safety Study
Multiple Dose Strengths
(N=60)

✓ Data readout 1H2019

Registration Trial*
(Phase 2/3 Trials)

Agitated Schizophrenia and Bipolar Patients

Agitated Alzheimer's Patients

Hyperactive Delirium

Opiate Withdrawal Symptoms

Adasuve Approval for Acute Treatment;
2 trials of 2 doses in 300+ patients, one in each indication;
Agitated Schizophrenia Patients: 344
Agitated Bipolar Patients: 314
Primary Endpoint: Reduction in PEC score from baseline

*Clinical Development plan subject to agreement with FDA

BXCL501 Program Summary

Broad market potential

- Low doses produce clinically measurable anti-agitation effects
- On track to initiate a registration trial for an indication for BXCL501 in 2019 with potential NDA filing in 2020
- Potential for multiple indications due to BXCL501's anti-agitation properties across different disease pathologies

Well capitalized to achieve multiple value inflection points through 2019

Dr. Vimal Mehta, CEO

BioXcel Therapeutics, New Haven, CT 06511

vmehta@bioxceltherapeutics.com

Exhibit 99.2

BioXcel Therapeutics Reports Positive Human Proof-of-Concept Data for Acute Treatment of Agitation in Patients with Alzheimer's Disease

Primary endpoint (safety and tolerability) met, with clinical benefit observed in 7 of 10 patients

Proof-of-Concept established in agitated patients across multiple underlying disorders including Alzheimer's Disease, Schizophrenia, and Delirium

Trial data, coupled with upcoming results of pharmacokinetic (bioavailability) BXCL501 study to support anticipated registration trial in 2019

Appoints Industry Veteran Dr. Robert Risinger as Vice President, Clinical Development to lead BXCL501 development

Conference call to discuss results and BXCL501 program on January 3, 2019 at 11:30 ET

NEW HAVEN, Conn., Jan. 3, 2019 — BioXcel Therapeutics, Inc. ("BTI") (Nasdaq: BTAI) today announced proof-of-concept data from its Phase 1 study of IV (intravenous) dexmedetomidine (Dex) for acute treatment of agitation in patients with Senile Dementia of the Alzheimer's Type (SDAT). The positive data from this Phase 1 trial provides evidence to support the continued clinical development of BXCL501 for the acute treatment of agitation under the accelerated Fast Track regulatory process. Agitation is common across all severities of Alzheimer's Disease, with an increasing prevalence as the disease progresses(1). 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 SDAT trial met its primary endpoint by identifying a safe dose of IV Dex that produced a mild arousable sedation, defined by a RASS(2) (Richmond Agitation Sedation Scale) score of -1. Data from this study, along with data from previously completed Phase 1 studies of IV Dex in agitated patients with schizophrenia and healthy elderly volunteers, is valuable in determining the optimal dose of BXCL501, a sublingual thin film formulation of Dex, being developed for the acute treatment of agitation.

This study enrolled a total of 14 SDAT patients. Ten patients in the treatment arm received IV Dex therapy, while 4 patients received placebo. In accordance with study designs used in previous participant populations, Dex treatment was begun at 0.1 mcg/kg/h and dose escalation occurred every 30 minutes by increasing the infusion rate by 0.1 mcg/kg/h to a maximum infusion of 0.5 mcg/kg/h. Such dosing allowed for the efficient determination of the optimal dose in each participant. The study demonstrated that 7 out of 10 patients in the treatment arm achieved arousable sedation (RASS score of -1), with only 1 of 4 patients in the placebo arm. The drug was well tolerated without any clinically significant adverse events.

Vincent O'Neill, MD, Chief Medical Officer of BTI, commented, "The results of this study further validate our belief that BXCL501 represents a product with the potential to treat acute agitation arising from a number of neuropsychiatric indications. IV Dex has now demonstrated that this selective and safe alpha 2a receptor agonist can benefit patients across multiple pathologies where acute agitation is an issue. We look forward to evaluating BXCL501, which recently received Fast Track designation from the U.S. Food and Drug Administration (FDA), in our ongoing first-in-human pharmacokinetic (bioavailability) study for which we expect top-line data in the first half of 2019."

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 Neuroscience Clinical Advisory Board added, "The results of this study demonstrate the ability of Dex to produce a rapid calming effect via its novel mechanism of action and support its potential as a safe and efficacious treatment for acute agitation. An easy-to-administer thin film formulation of BXCL501 could provide a much-needed treatment for agitation in patients across a range of neurological and psychiatric disorders."

BXCL 501 Program Update:

BTI is currently dosing subjects 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 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 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 in patients suffering 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.

BTI Team Update:

Additionally, the Company announced the appointment of Robert Risinger, MD, as Vice President Clinical Development. Reporting to Dr. Vincent O'Neill, Dr. Risinger will lead the clinical development of BXCL501. He joins BTI with more than 10 years of neuropsychiatric drug development experience at companies including Alkermes, Bristol-Myers Squibb, Johnson & Johnson and most recently NeuroRx Pharmaceuticals. Prior to his industry career, Dr. Risinger was an Assistant Professor of Psychiatry and Behavioral Medicine at Medical College of Wisconsin. He also served as a Major and Staff Psychiatrist in the U.S. Air Force. He holds an MD from the University of Pittsburgh School of Medicine and completed his Psychiatric Residency at Emory University School of Medicine. The hiring of Dr. Risinger brings BioXcel Therapeutics' total employees to nearly 20.

Dr. Risinger commented, "I am thrilled to join BTI at such a critical juncture. The data we have generated to-date is extremely compelling and suggests that BXCL501 has the potential to demonstrate a superior therapeutic profile and route of administration compared to any other alpha 2a receptor agonist. The data from this study, coupled with previously-generated data in healthy volunteers, as well as agitated patients with schizophrenia, provides a strong rationale to launch a potential registration trial of BXCL501."

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(1) https://institute.progress.im/en/content/alzheimer%E2%80%99s-disease-and-agitation
(2) RASS is a 10-point (+4 "combative" to -5 "unarousable") medical scale used to measure the agitation or sedation level of a patient.

Conference Call:

BTI will host a conference call today, January 3, 2019, at 11:30 a.m. Eastern Time to discuss the results of this study and BXCL501 Program. Interested investors can access the call by dialing 800-239-9838 in the U.S. and Canada, or 323-994-2093 internationally. The call, along with a slide presentation to accompany the call, will be available via a live, listen-only webcast at http://public.viavid.com/index.php?id=132677, and archived for 30 days. For those unable to participate, a replay of the call will be available until February 3, 2019. To access the replay, please dial 844-512-2921 in the U.S. and Canada, or 412-317-6671 internationally, and enter passcode 2933928.

About BXCL501:

BXCL501 is a first in class, sublingual film of dexmedetomidine, a selective alpha 2a 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. 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 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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