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) **April 14, 2020**

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)	(IRS Employer Identification No.)

555 Long Wharf Drive
New Haven, CT 06511
(Address of principal executive offices)(Zip Code)

(475) 238-6837
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	BTAI	The Nasdaq Capital Market

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 7.01. Regulation FD Disclosure.

BioXcel Therapeutics, Inc. (the "Company") will be participating in various upcoming meetings with investors and analysts. A copy of the Company's presentation materials that will be used at these meetings is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. These presentation materials are also available through the "Investors" page of the Company's website at *www.bioxceltherapeutics.com*.

The information in Item 7.01 of this Current Report on Form 8-K, including the presentation materials reference herein, shall not be deemed "filed" for 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, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

Business Update

On April 14, 2020, the Company provided the following updates regarding its clinical trials and business operations in light of the COVID-19 pandemic:

- The Company has taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention (CDC) and the State of Connecticut to protect the health and safety of its employees and the community. In particular, the Company has implemented a work-from-home policy for all employees. and has restricted on-site activities to certain chemical, manufacturing and control (CMC) and clinical trial activities. The Company is continuing to assess the impact of the COVID-19 pandemic to best mitigate risk and continue the operations of its business.

- The Company is working closely with its clinical sites to monitor the potential impact of the evolving COVID-19 pandemic. The Company remains committed to its clinical programs and development plans. As of now, the Company has not experienced any significant delays to its ongoing or planned clinical trials; however, this could rapidly change.

- Consistent with existing guidance, the Company continues to enroll patients in its two Phase 3 SERENITY trials and assess data for dose escalation in its Phase 1b/2 TRANQUILITY trial. The Company expects to provide data readouts for trials involving its product candidates BXCL501 and BXCL701 as summarized in slides 19 and 26 in Exhibit 99.1 attached hereto, which slides 19 and 26 are incorporated herein by reference. Notwithstanding the Company's current expected timing and milestones, the ability to continue to enroll patients, conduct patient follow-up and provide data readouts as planned may be impacted by the COVID-19 pandemic.

Supplemental Risk Factor

In addition, in light of recent developments relating to the COVID-19 pandemic, the Company is supplementing the risk factors previously disclosed in Part I., Item 1A. of its Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission on March 9, 2020, to include the following risk factor under the heading "Risk Factors — Risks Related to Our Business and Industry":

The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, the novel coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has been declared a pandemic and has spread to multiple global regions, including the United States and Europe. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have implemented a work-from-home policy for all employees has restricted on-site activities to certain chemical, manufacturing and control (CMC) and clinical trial activities.

As a result of the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations resulting from restrictions on our on-site activities;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Additionally, concerns over the economic impact of COVID-19 pandemic have caused extreme volatility in financial and other capital markets which has and may continue to adversely impact our stock price and our ability to access capital markets.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements regarding the impact of COVID-19 on our business and operations and enrollment of patients in, timing of and release of results for our clinical trials of BXCL501 and BXCL701 in light of the COVID-19 pandemic. Forward-looking statements may be identified by words such as "anticipates," "believe," "continue," "expect," "intend," "may," "plan to," "potential," "will," and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including without limitation, the impact of the COVID-19 pandemic on the status, enrollment, timing and results of our clinical trials and the continuity of our business; and the other risks referred to under the section "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as such factors may be updated from time to time in our other filings with the SEC, which filings are accessible on the SEC's website at *www.sec.gov* and the Investors page of our website at *www.bioxceltherapeutics.com.* All forward-looking statements speak only as of the date of this Current Report on Form 8-K and, except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	BioXcel Therapeutics, Inc., April 2020 Presentation

SIGNATURES

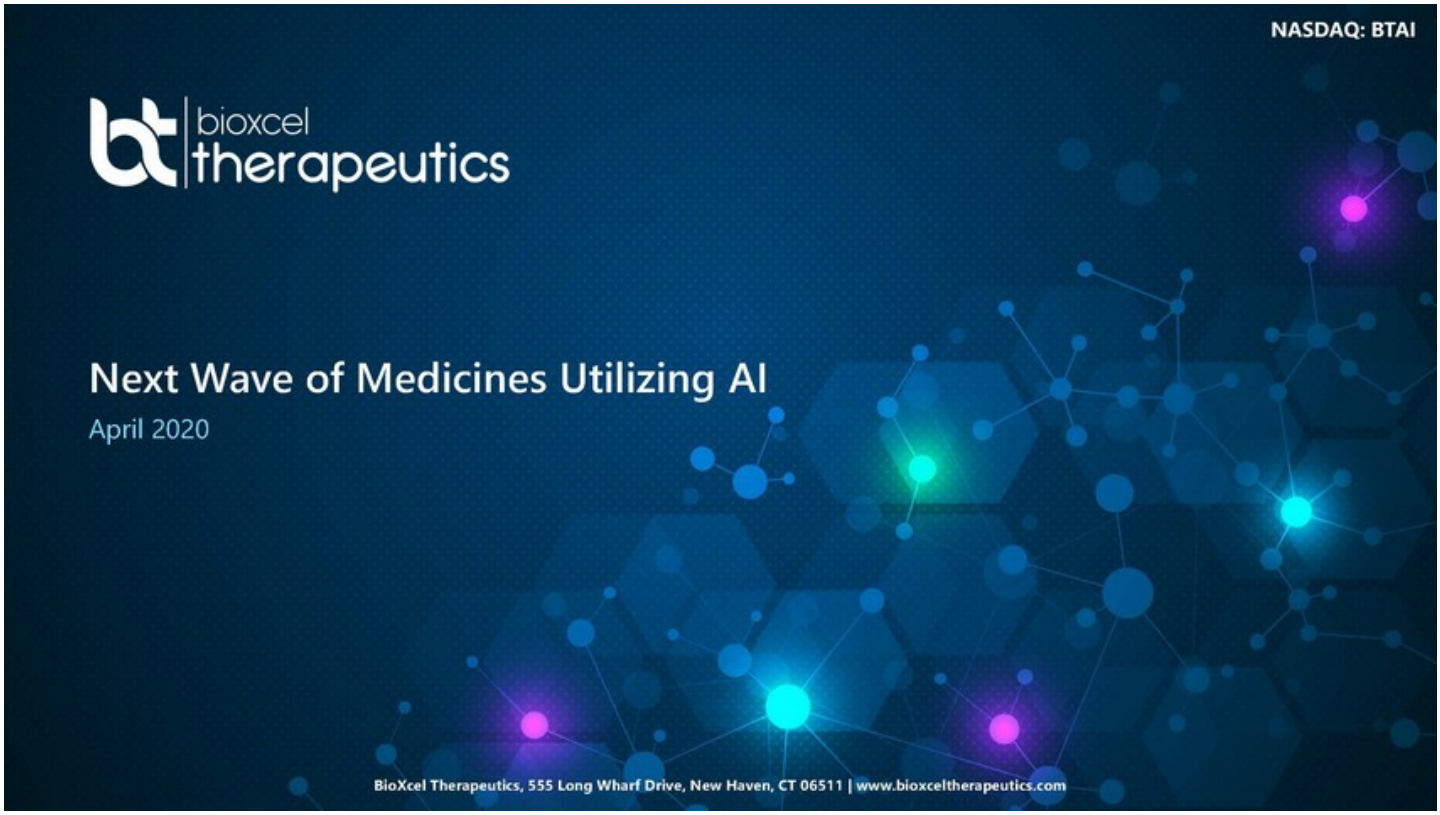
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 14, 2020

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1


NASDAQ: BTAI
bioxcel therapeutics
Next Wave of Medicines Utilizing AI
April 2020
BioXcel Therapeutics, 555 Long Wharf Drive, New Haven, CT 06511 | www.bioxceltherapeutics.com

Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, but are not limited to, statements that relate to the advancement and development of BXCL501 and BXCL701, anticipated milestones, clinical development plans, the availability and results of data from clinical trials, expected patent terms and other information that is not historical information. When used herein, words including "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 BTI's current expectations and various assumptions. BTI believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BTI 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, its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of BXCL501 and BXCL701 and other product candidates; it ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; its approach to the discovery and development of product candidates based on EvolverAI is novel and unproven; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as supplemented by its Current Report on Form 8-K filed on April 14, 2020 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors page of its website at www.bioxceltherapeutics.com.

These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While BTI may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing BTI's views as of any date subsequent to the date of this presentation.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and we make no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. While we believe our own internal research is reliable, such research has not been verified by any independent source.

Overview

SERENITY Program Pivotal Readouts Expected in Mid-2020

AI-Powered Drug Development

- Identifies novel opportunities for clinical stage compounds
- Improves R&D economics
- Potentially reduces development timelines

Neuro Program

BXCL501—Sublingual Thin Film for Acute Treatment of Agitation

- Phase 3 schizophrenia and bipolar trials (SERENITY I & II) initiated; readouts expected mid-2020
- Phase 1b/2 dementia trial (TRANQUILITY) initiated; readout expected mid-2020
- Phase 1b/2 opioid withdrawal trial (RELEASE); preparing to initiate

Immuno-oncology Program

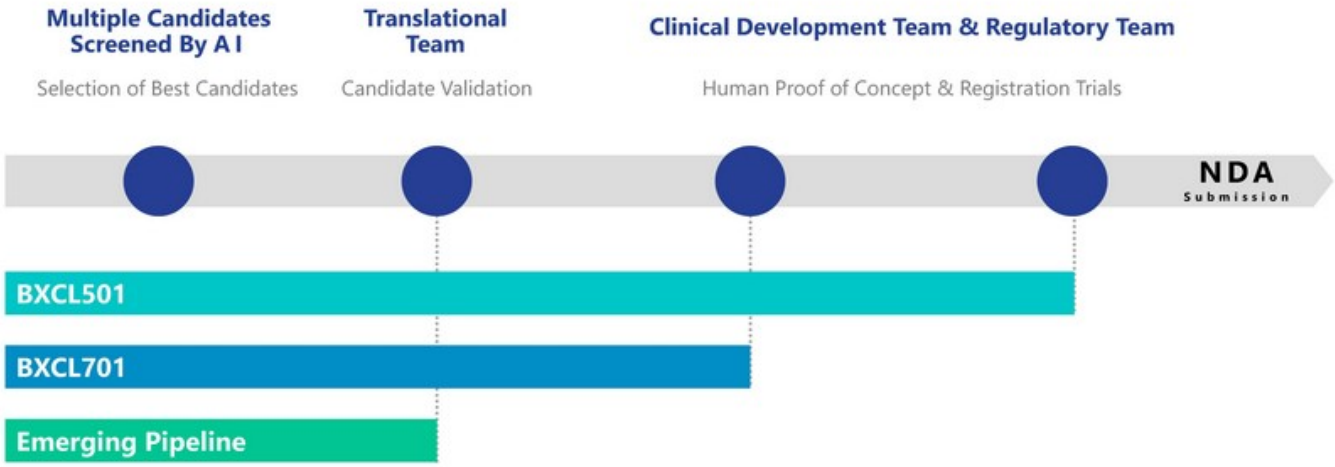
BXCL701—Targeting Rare Cancers

- Phase 1b/2 double combo trial in Neuroendocrine Prostate Cancer (tNEPC) ongoing
- MD Anderson led Phase 2 basket trial in advanced solid tumors
- Phase 1b/2 triple combo trial in pancreatic cancer initiation expected 2020

Strengthened balance sheet in Feb. 2020 through follow-on offering raising $60 million in net proceeds

AI Platform May Reduce Development Timelines and Cost

4–5 Year Development Cycle



Pipeline

Neuropsychiatry	
BXCL501	
Acute agitation in schizophrenia/bipolar	SERENITY I & II Trials (Phase 3)
Acute agitation in dementia	TRANQUILITY Trial (Phase 1b/2)
Opioid withdrawal	RELEASE Trial (IND Clearance)
Delirium	Clinical Planning
KalmPen™ (Single-use IM)	
Severe agitation	Formulation Development
Wearable Device (+BXCL501)*	
Pre & post-agitation in dementia	Clinical Feasibility Study
BXCL501 + combination	
Chronic agitation in dementia	Formulation Development
Immuno-oncology	
BXCL701	
Neuroendocrine Prostate Cancer (tNEPC) Double Combination	Phase 1b/2
Advanced Solid Tumor Types (MD Anderson Led)	Phase 2
Pancreatic Cancer Triple Combo	Phase 1b/2

*Regulatory path to be determined; device + drug combination to be evaluated after validation of predictive algorithm

bioxcel therapeutics

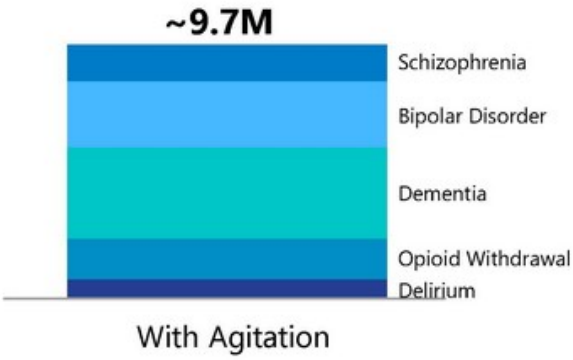
BXCL501:

Potential First in Class Sublingual Thin Film Dexmedetomidine (Dex) for Acute Treatment of Agitation

Agitation: A Common Phenomenon Associated with Psychiatric Conditions

High Unmet Medial Need in the U.S.

- 9.7 million suffer each year [1]
  - Schizophrenia/bipolar: 3.1M
  - Dementia: 4M
  - Opioid withdrawal: 1.6M
  - Delirium: 1M [2]
- Patients experience multiple episodes per year
- $40 billion per year health care burden
- Agitation episodes can put both the patient and caregiver at risk



1. Internal company estimates based on analysis of primary market research, prescription database, and published data.
2. Agitated Delirium in ICU, does not include hyperactive delirium in medical and surgical wards

Broad Market Potential Across Centers

Where Neuropsychiatric Patients are Treated

Hospitals
Medical + Neuro + Psych Wards
Psychiatric Hospitals

Urgent Care Centers

Mental Clinics
Neurology/Mental Health
Crisis Care

Emergency Departments
General, Psychiatric

Nursing Homes
Assisted Living

Current Treatment Options Fail to Address the Underlying Condition

Current Therapies Are Suboptimal

- Verbal de-escalation is used as first line treatment
- Injectables are invasive with severe side effects
- Antipsychotic drugs have black-box warning for elderly
- Restraining can damage the caregiver/patient relationship
  - Requires 1:1 observation
- Over-sedation is a major issue – patients cannot be properly evaluated

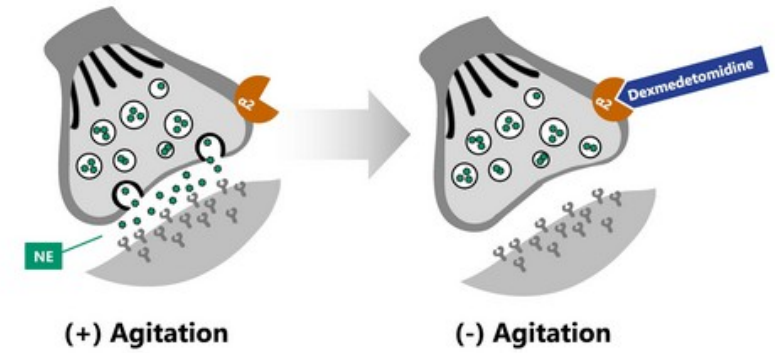
BXCL501's product profile offers significant advantages over the standard of care

Fast Track Designation

BXCL501 for treatment of acute agitation associated with schizophrenia, bipolar disorder, or dementia

BXCL501: Proprietary Sublingual Thin Film of Dex*
Designed to Block Driver of Agitation

Dexmedetomidine MoA



(+) Agitation (-) Agitation

Norepinephrine (NE)

*Dexmedetomidine

Novel Mechanism May Directly Target Causal Agitation

- Dex activates at the alpha-2a receptor preventing the release of norepinephrine

Highly Differentiated from Current Treatments

- ✔ Easy to administer, sublingual formulation
- ✔ Non-traumatic
- ✔ Rapid onset of action, without excessive sedation (observed in clinical studies)
- ✔ Non-invasive
- ✔ Self-administered by patients

bioxcel therapeutics

Proprietary, Easy-to-Administer Formulation

Proprietary, Immediate Delivery, Sublingual Thin Film Product

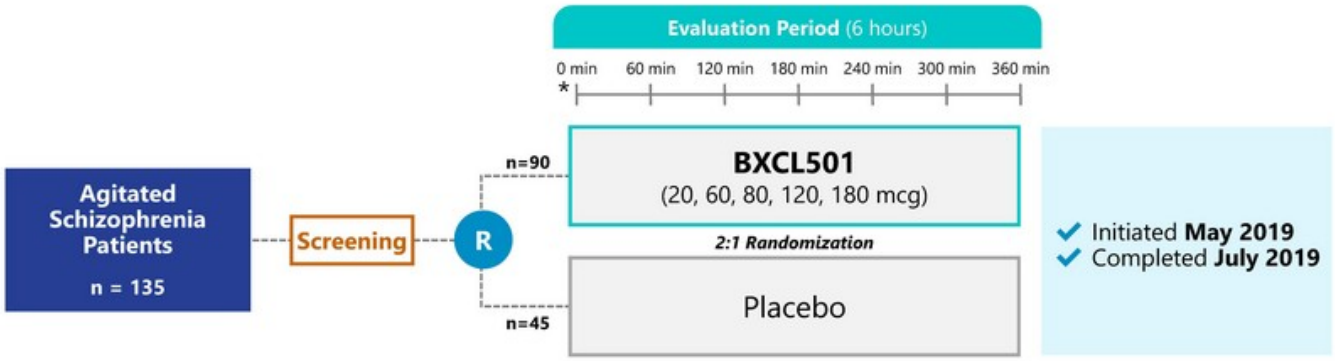
- Muco-adhesion properties designed for optimizing compliance
- Adaptable technology enables broad dose range
- Flexible for potential combination of multiple drugs on a single film
- Expected patent term until 2039 -2041

Transitioned to Registrational Drug Product Process

- Manufacturing Phase 3/registrational batches
- Commercial scale-up planned for product launch

Successful Phase 1b Clinical Trial in Agitated Schizophrenia Patients

Assessing Agitation Episodes in Schizophrenia

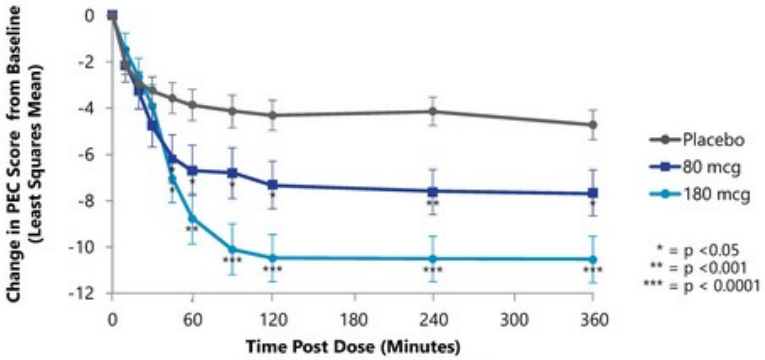


Primary Endpoint: Change from Baseline in PEC Score (PANSS-Excitatory Component) at 2 Hours

* Patients Dosed

Primary Endpoint: Statistically Significant Change in PEC Score

Clinically Meaningful, Rapid and Durable Responses



Time = 120 Min (Primary Endpoint)

Drug/Dose	#	% Responders (Reduction in PEC of ≥ 40%)	Mean Change in PEC Score	P-Value
Placebo	N=36	28%	-4.5	
BXCL501 (180 mcg)	N=18	89%	-10.8	< 0.0001
BXCL501 (120 mcg)	N=18	67%	-9.2	0.0003
BXCL501 (80 mcg)	N=18	56%	-7.1	0.0152
BXCL501 (60 mcg)	N=18	39%	-6.0	0.1227

* The lowest dose tested, 20 mcg (not shown) was repeated in subjects who did not achieve response criterion

Safety Results in Phase 1b Study

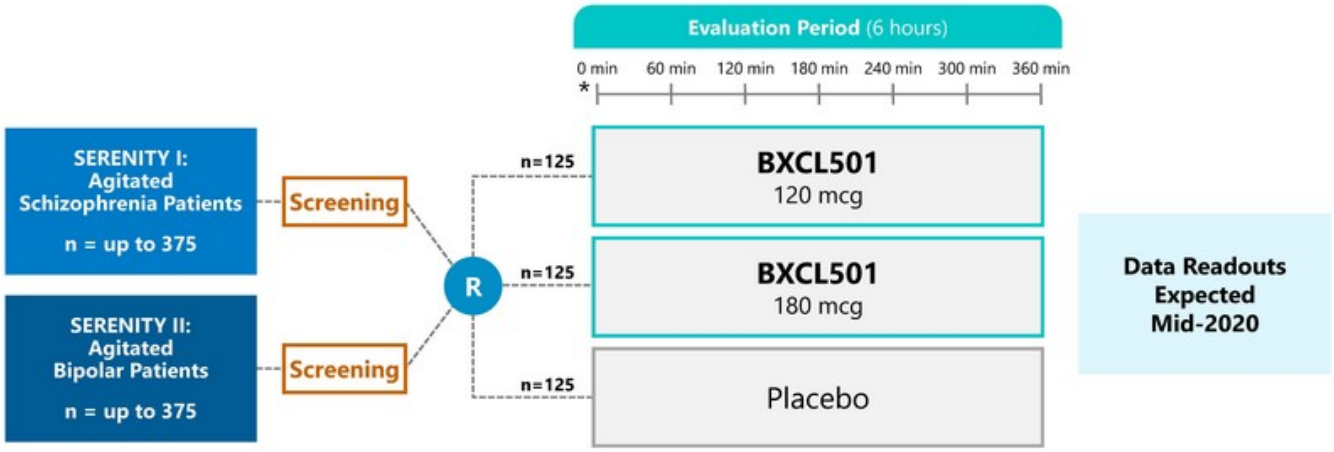
Well-tolerated with no serious or severe adverse events

Most common adverse events: mild somnolence and dry mouth

Maximum tolerated dose was not reached

All subjects (100%) were able to self-administer the film

SERENITY Phase 3 Pivotal Trials Initiated: Adaptive Design

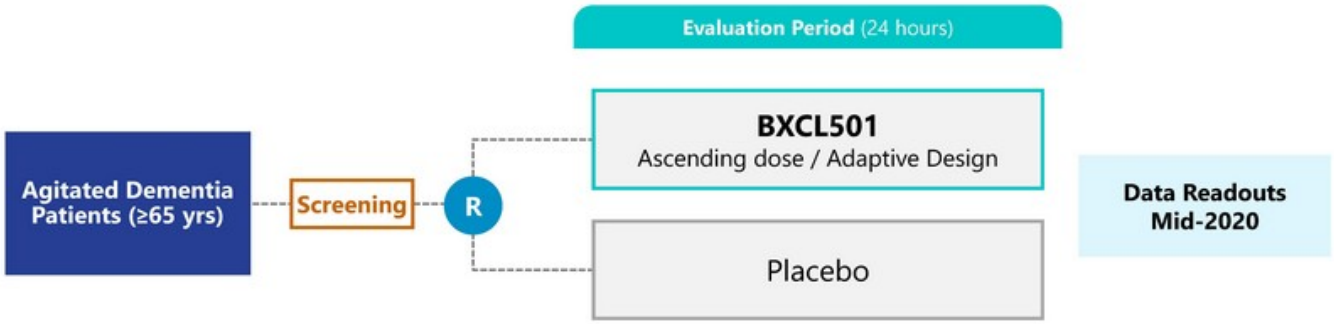


Primary Endpoint: Change from Baseline in PEC Score (PANSS-Excitatory Component) at 2 Hours

* Patients Dosed

TRANQUILITY Phase 1b/2 Trial Initiated – Dementia

Assessing Agitation Episodes in Dementia



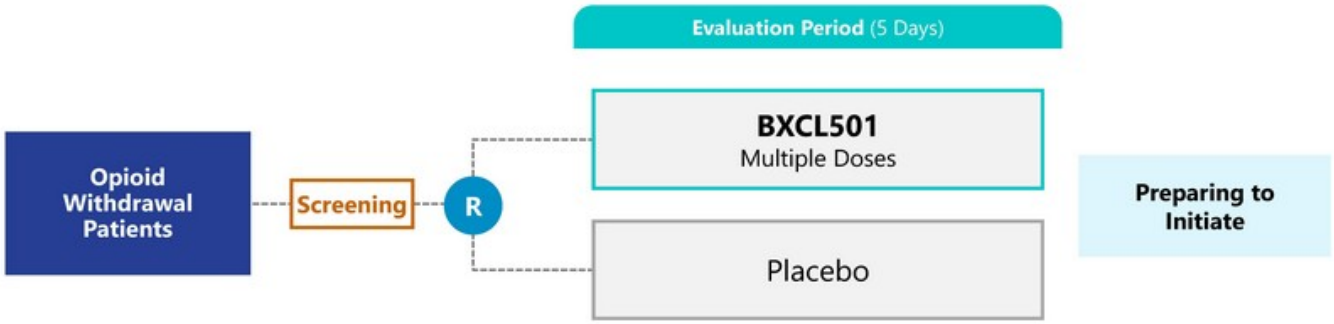
Key Inclusion Criteria

- Dementia (all forms including AD)
- Clinically significant agitation

Efficacy Endpoints

- PAS: Pittsburgh Agitation Scale
- PEC: PANSS Excitatory Component
- CMAI: Cohen-Mansfield Agitation Inventory (modified)

RELEASE Phase 1b/2 Trial – Opioid Withdrawal



Key Inclusion Criteria and Design

- Street/prescription opiate abusers with signs and symptoms of opiate withdrawal before entry
- Double-blinded, placebo-controlled dose escalation design

Efficacy Endpoints

- Pharmacokinetics, Safety and Tolerability
- COWS: Clinical Opiate Withdrawal Scale
- SOWS: Short Opiate Withdrawal Scale of Gossop

Neuroscience Program Strategy

Preagitation

Prophylaxis or Prevention of Agitation

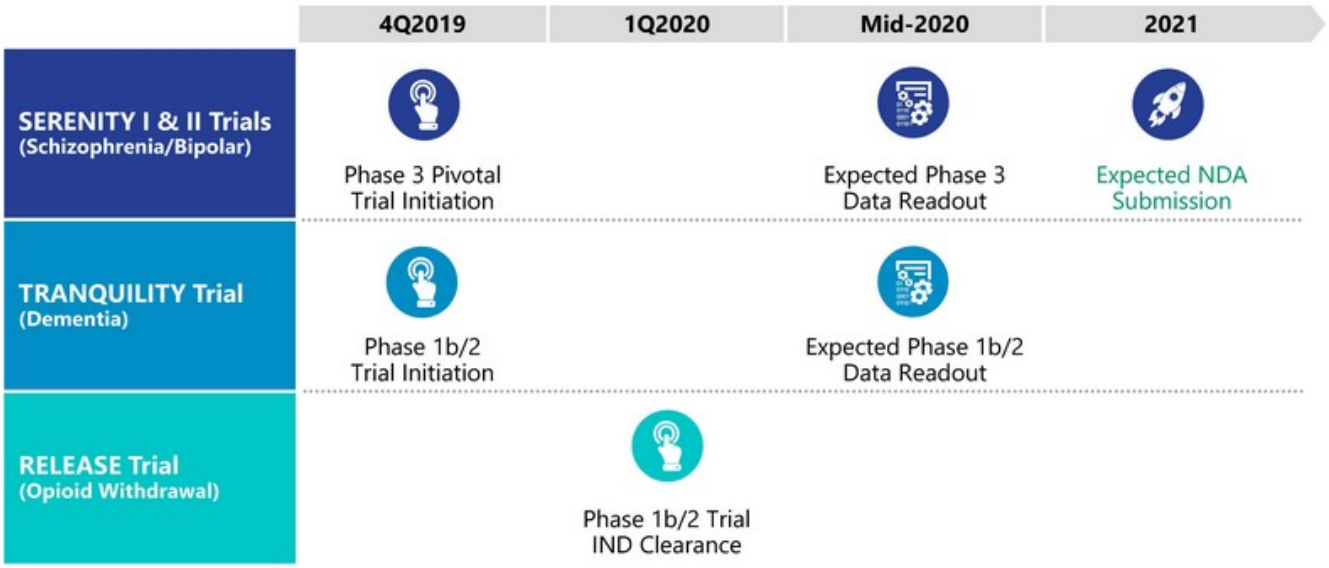
Mild to Moderate Agitation

- Schizophrenia/Bipolar (NDA)
- Dementia (sNDA)
- Opioid Withdrawal (sNDA)
- Delirium (sNDA)

Severe Agitation/Aggression

IM Formulation Development

BXCL501 Product Development Milestones



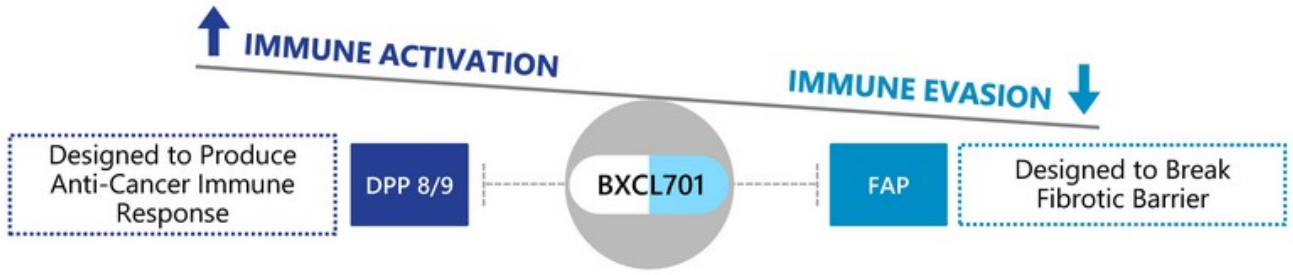
bioxcel therapeutics

BXCL701

Potential First-in-Class Oral IO Therapy

Orally Administered Investigational Activator of Systemic Innate Immunity Pathway

Dual MoA designed to inhibit DPP 8/9 & FAP



- Current approved immunotherapies struggle to address tumors that appear "cold" or uninflamed
- BXCL701 is designed to stimulate the innate immune system, facilitating a strong adaptive anti cancer immune response – turning "cold" tumors "hot"

BXCL701 Clinical Development Strategy

Multiple Opportunities to Evaluate Patient Outcomes

1. **Treatment Emergent Prostate Cancer (tNEPC):** Phase 1b/2 trial of BXCL701 and KEYTRUDA

2. **Pancreatic Cancer:** Triple combination (BXCL701, bempegaldesleukin and BAVENCIO®) trial

3. **Solid Tumors Responsive to CPIs*:** Open-label Phase 2 basket trial led by MD Anderson

* CPI: Check Point Inhibitors

Phase 1b/2: In Combination with KEYTRUDA to Treat tNEPC

1

Ongoing Safety Run-in*
Safety/PD/Immune-phenotyping

KEYTRUDA (pembrolizumab)

- Dose finding study in combination with KEYTRUDA®
- Preliminary pharmacokinetics of BXCL701 are within expectations based on prior data
- Initial data readout expected 1H 2020

Planned Phase 2 Expansion
(N=30)

- **Simon 2-stage:**
  15+15
- **Primary Endpoint:**
  Composite response rate: Target > 15%
- **Secondary Endpoint:**
  DoR, PFS, OS
- **Exploratory Endpoint:**
  Effect on immune cells (MDSC, T-cells, neutrophils)

* Initial safety data presented at "The 26th Annual Prostate Cancer Foundation Scientific Retreat at the La Costa Resort in Carlsbad, CA"

Pancreatic Cancer: Triple Combination Trial

2

Triple Combination*
Phase 2 Expansion (n=30)

BXCL701
NKTR-214
Avelumab

- **Simon 2-stage:**
  15+15
- **Primary Endpoint:**
  ORR Combination
- **Secondary Endpoint:**
  DoR, PFS, OS
- **Exploratory Endpoint:**
  Effect on immune cells (MDSC, T-cells, neutrophils)

*BXCL701 phase expected to be initiated following Nektar and Pfizer's safety run-in trial of a double combination of NKTR-214 and avelumab and the outcome of that trial.

Expanding Study of BXCL701: Open-label Basket Trial with Keytruda

3

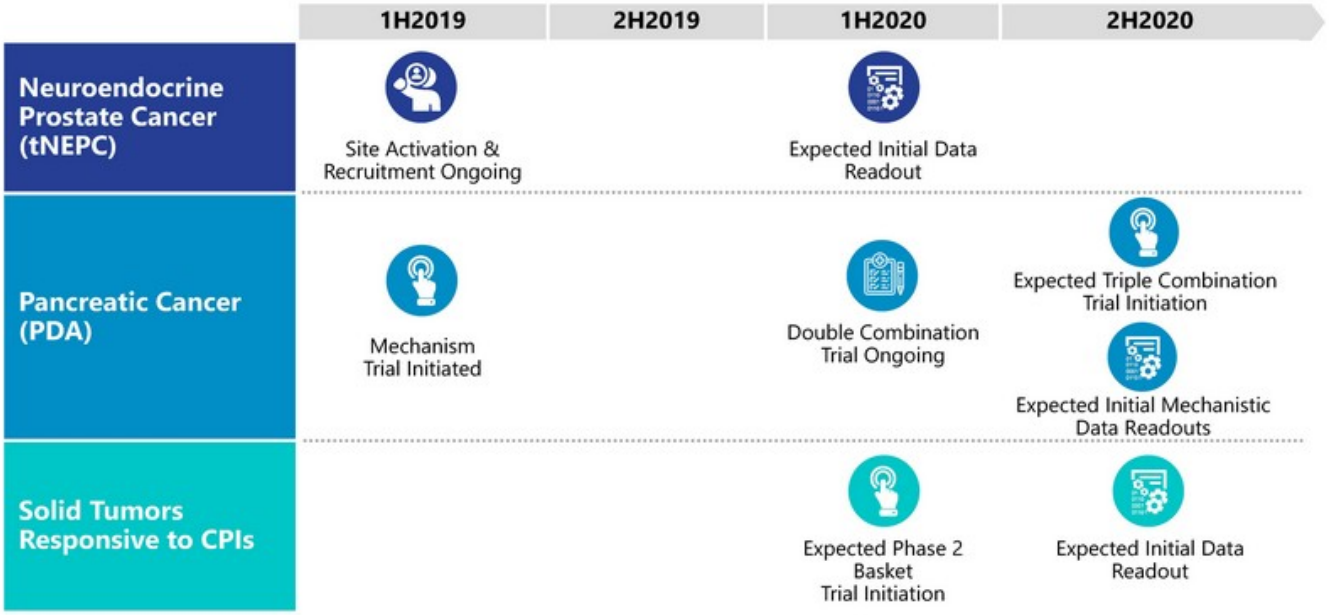
CPI Responsive Solid Tumor Study

KEYTRUDA (pembrolizumab)

- Cohort A: evaluating patients who are naïve to checkpoint therapy
- Cohort B: evaluating patients who have failed or are refractory to checkpoint therapy
- **Outcome measures:** ORR, progression-free-survival, overall survival, duration of response, and the safety of combined treatment

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

BXCL701 Program Milestones



bioxcel therapeutics

Thank You!

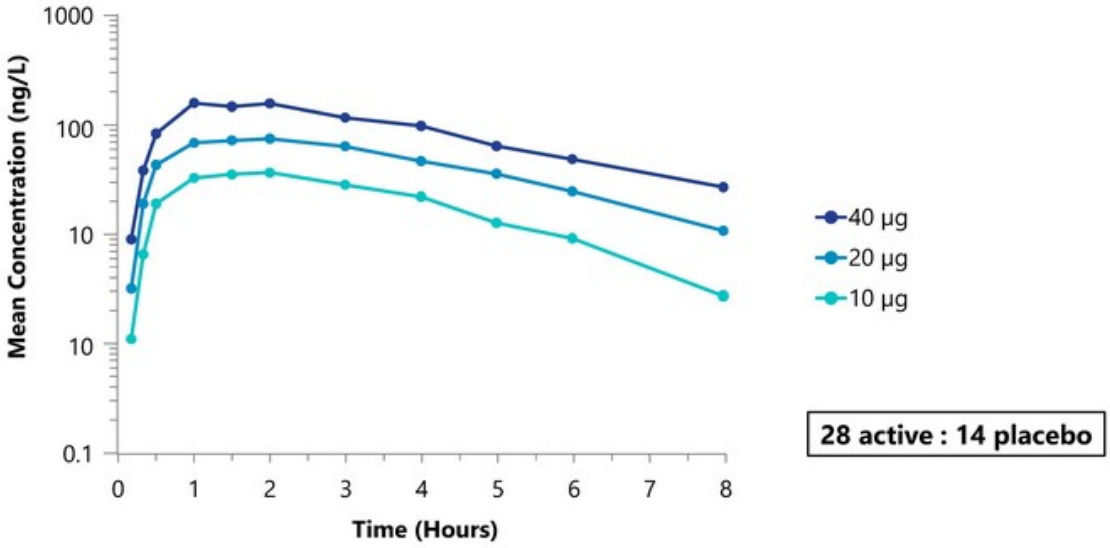
Dr. Vimal Mehta, CEO
BioXcel Therapeutics, New Haven, CT 06511
vmehta@bioxceltherapeutics.com

bioxcel therapeutics

Appendix

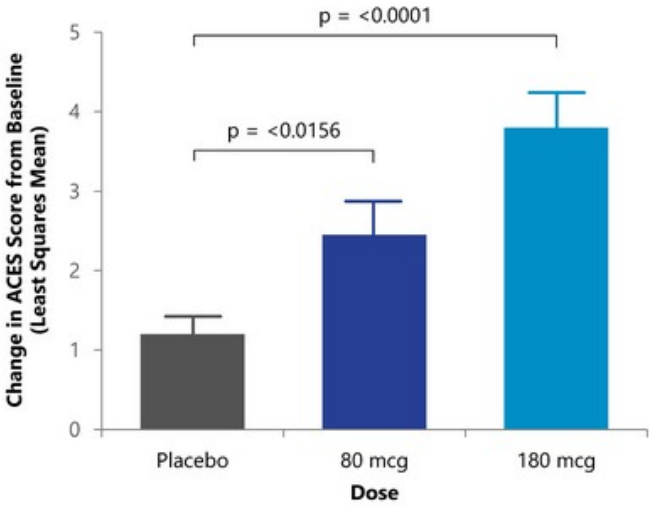
Predictable and Dose Proportional PK Observed in Phase I Study

Phase I Clinical Studies in 42 Healthy Volunteers



Secondary Evaluation: Change in ACES from Baseline

Consistent with Primary Endpoint



Drug/Dose	#	Mean Change in ACES Score from Baseline	P-Value
Placebo	N=36	1.20	
BXCL501 (180 mcg)	N=18	3.94	< 0.0001
BXCL501 (120 mcg)	N=18	3.11	0.0005
BXCL501 (80 mcg)	N=18	2.33	0.0156
BXCL501 (60 mcg)	N=18	2.11	0.0750

* The lowest dose tested, 20 mcg (not shown) was repeated in subjects who did not achieve response criterion

The ACES consists of a single item that rates overall agitation and sedation at the time of evaluation, where 1 indicates marked agitation; 2, moderate agitation; 3, mild agitation; 4, normal behavior; 5, mild calmness; 6, moderate calmness; 7, marked calmness; 8, deep sleep; and 9, unarousable.