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)
March 11, 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 Items.

BioXcel Therapeutics, Inc. (the "Company") has prepared presentation materials (the "Presentation Materials") that management intends to use from time to time on and after March 11, 2019, in presentations about the Company's operations and performance. The Presentation Materials are attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation Materials

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: March 12, 2019

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1


bioxcel
therapeutics
(NASDAQ: BTAI)
Next Wave of Medicines
March 2019
BioXcel Therapeutics, 555 Long Wharf Drive, New Haven, CT 06511 | www.bioxceltherapeutics.com

Safe Harbor Statement

This document may contain forward-looking statements. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “intend,” “anticipate,” believe,” “estimate” and “continue” or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements.

We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Factors that may cause such differences include, but are not limited to, the uncertainties associated with our limited operating history, product development, the regulatory approval process of the FDA, the market for our product candidates, the success of BXCL501 and BXCL701, the risks associated with dependence upon key personnel and the need for additional financing. Except as required by law, we do not assume any obligation to update forward-looking statements as circumstances change.

These forward-looking statements are based on certain assumptions and are subject to risks and uncertainties, including those described in the “Risk Factors” section and elsewhere in the Company’s filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov and https://ir.bioxceltherapeutics.com/all-sec-filings.

BioXcel Therapeutics Investment Highlights

Developing high value therapeutics in neuroscience and immuno-oncology utilizing a novel artificial intelligence platform

BXCL501
First-in-Class Sublingual
Thin Film for Acute
Treatment of Agitation

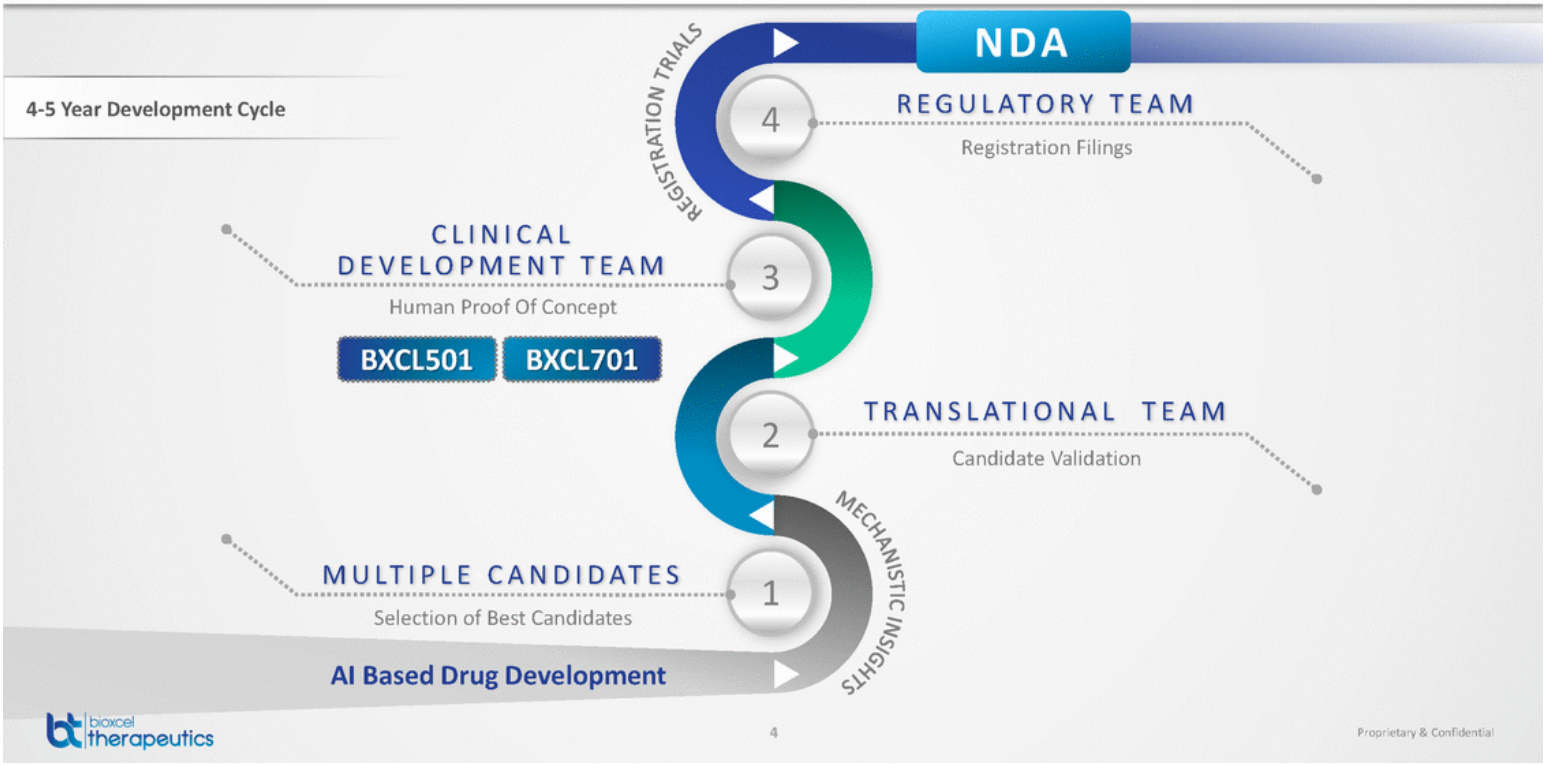
BXCL701
First-in-Class
Targeting Rare Cancers
First Clinical Partnership

Pfizer
MERCK
NEKTAR

AI-POWERED DRUG DEVELOPMENT
Improves R&D Economics:
Development Efficiency
and Probability of Success

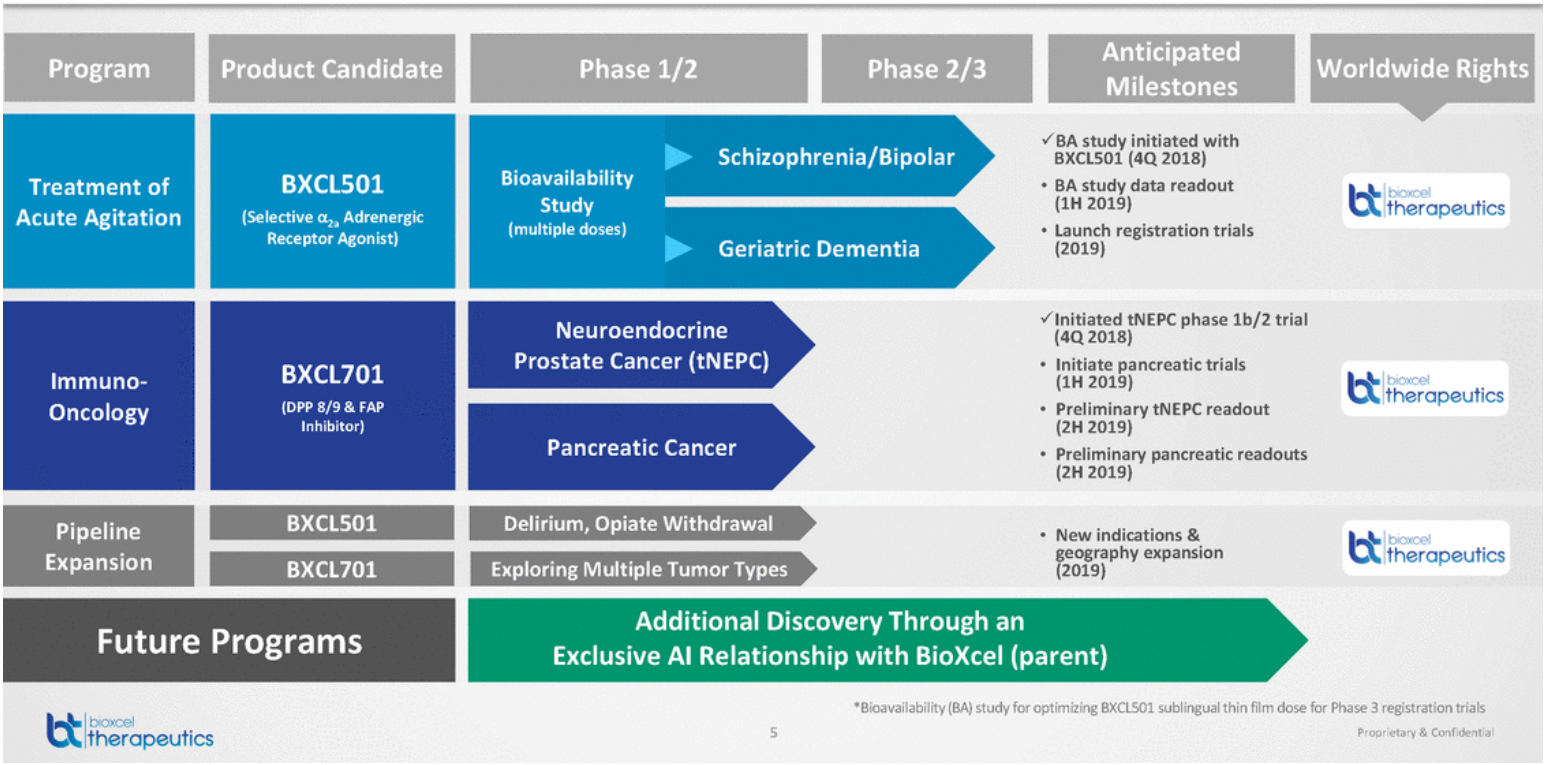
BTI is Unleashing the Power of AI Across the Entire R&D Value Chain

Opportunity to generate multiple NDAs



BioXcel Therapeutics Pipeline: Rapid Human PoC and Development Path

First-in-class neuroscience and immuno-oncology pipeline with multiple near-term milestones



*Bioavailability (BA) study for optimizing BXCL501 sublingual thin film dose for Phase 3 registration trials

Clinical Programs

BXCL501: *First in Class Sublingual Thin Film Dexmedetomidine (Dex) for Acute Treatment of Agitation*

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**

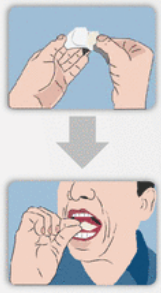
BXCL501: Sublingual Thin Film Formulation of Dexmedetomidine (Dex)

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)

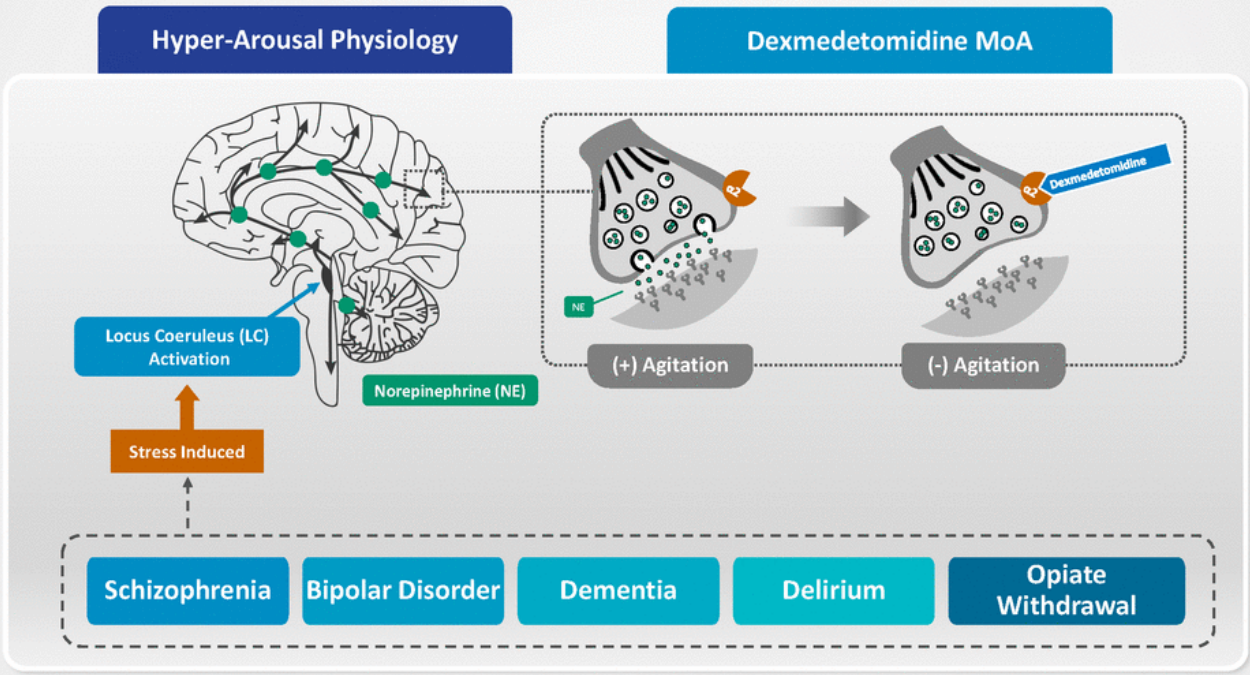
- Prescribed to **8M+ patients**
- Studied in **120 clinical trials**
- **Wide therapeutic index:**

For Sedation in ICU Setting:

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

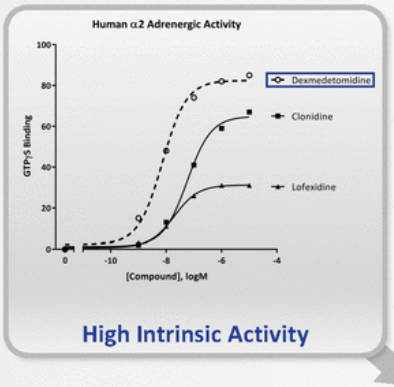
Dexmedetomidine Mechanism of Action

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

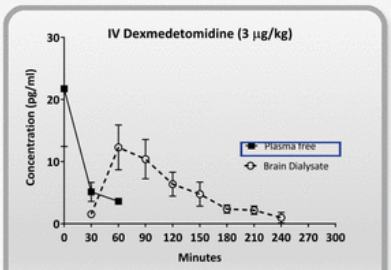


Pre-Clinical Data to Support Clinical Development Plan

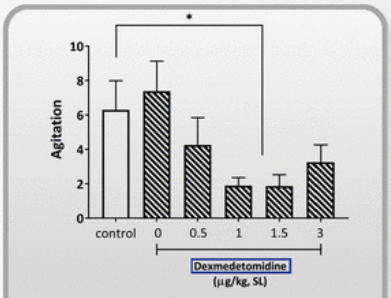
Properties of Dexmedetomidine in Cells, Brain Levels, and Efficacy Models



High Intrinsic Activity



High Brain to Plasma Ratio



Agitation reduction without sedation

Translation of non-clinical data to clinical activity in human PoC

Positive Human Proof of Concept in Treating Agitation

IV Dex data from 105 patients: four disease pathologies (89) & healthy volunteers (16)

SCHIZOPHRENIA

- 14 patient study
  - [10 treatment + 4 placebo]
- **Clinical benefit observed in 9/10 treated**
  - RASS score of -1
  - PEC* score of 7 or below

90% Response

**PEC = Positive and Negative Symptom Scale-Excitatory Component*

adasuve

ALZHEIMERS

- 14 patient study
  - [10 treatment + 4 placebo]
- **Clinical benefit observed in 7/10 treated**
  - RASS* score of -1

70% Response

**RASS = Richmond Agitation Sedation Scale*

105 Patient Experience

DELIRIUM

- 132 patients
  - [46 refractory to haloperidol]
- **46/46** haloperidol refractory patients **responded to IV Dex** in reducing agitation

100% Response

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

OPIOID WITHDRAWAL

- 15 subject study
  - [10 treatment + 5 placebo]
- **Clinical benefit observed** in **10/10 treated**
  - 50% reduction in COWS total score

100% Response

**COWS = Clinical Opiate Withdrawal Scale*

lucemyra

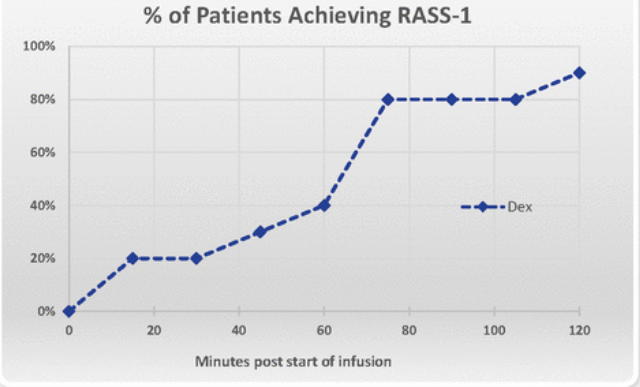
Human Proof of Concept 1: IV Dex Reduces Agitation in Schizophrenia Patients

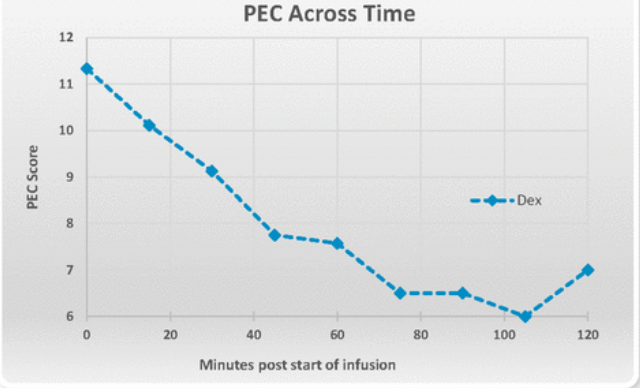
Study results announced Nov 2018: primary endpoint met

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

90% Response





- 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

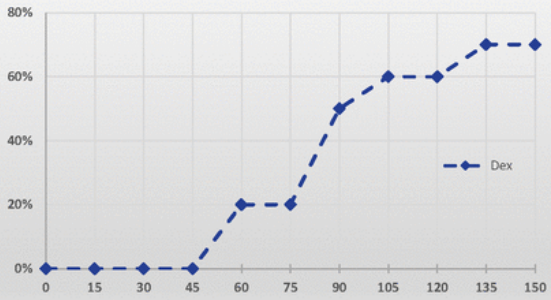
Study results announced Jan 2019: primary endpoint met

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

70% Response

% 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

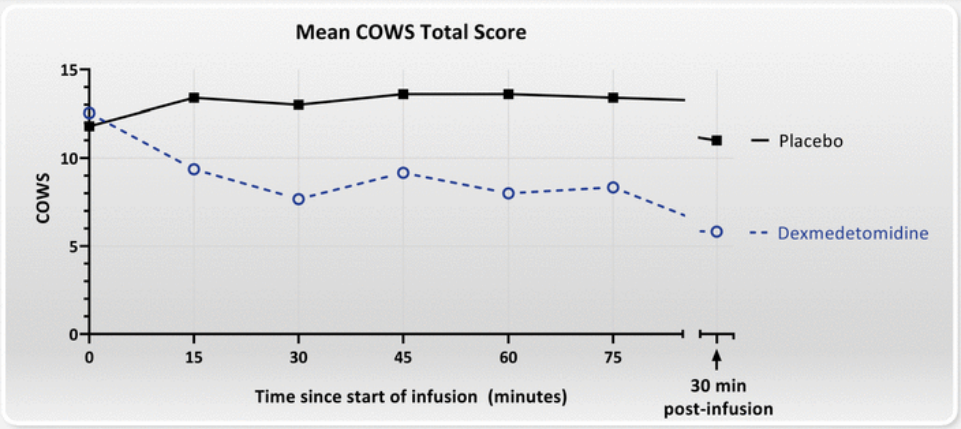
Human Proof of Concept 3: IV Dex Reduces Symptoms in Opioid Withdrawal

Study results announced Feb 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
- 15 patients [10 treatment + 5 placebo]
- Primary endpoint: Dose achieving ≥50% reduction in COWS score

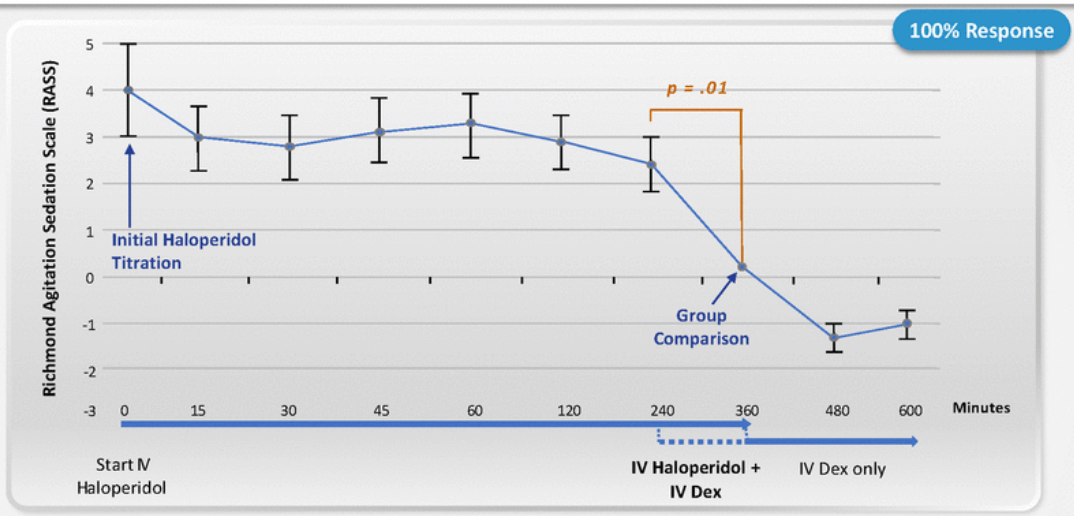
100% Response



- 10/10 Patients Responded to Treatment
- No Responders in the Placebo Arm
- No clinically meaningful cardiovascular effects
- Therapeutic levels not associated with sedation

Human Proof of Concept 4: 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 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
- **Data readout in 2Q19**

BXCL501 Integrated Clinical Development Plan

Acute agitation studies: short with easily measurable clinical endpoints

Sublingual Thin Film

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

✓ Data readout 2Q19

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

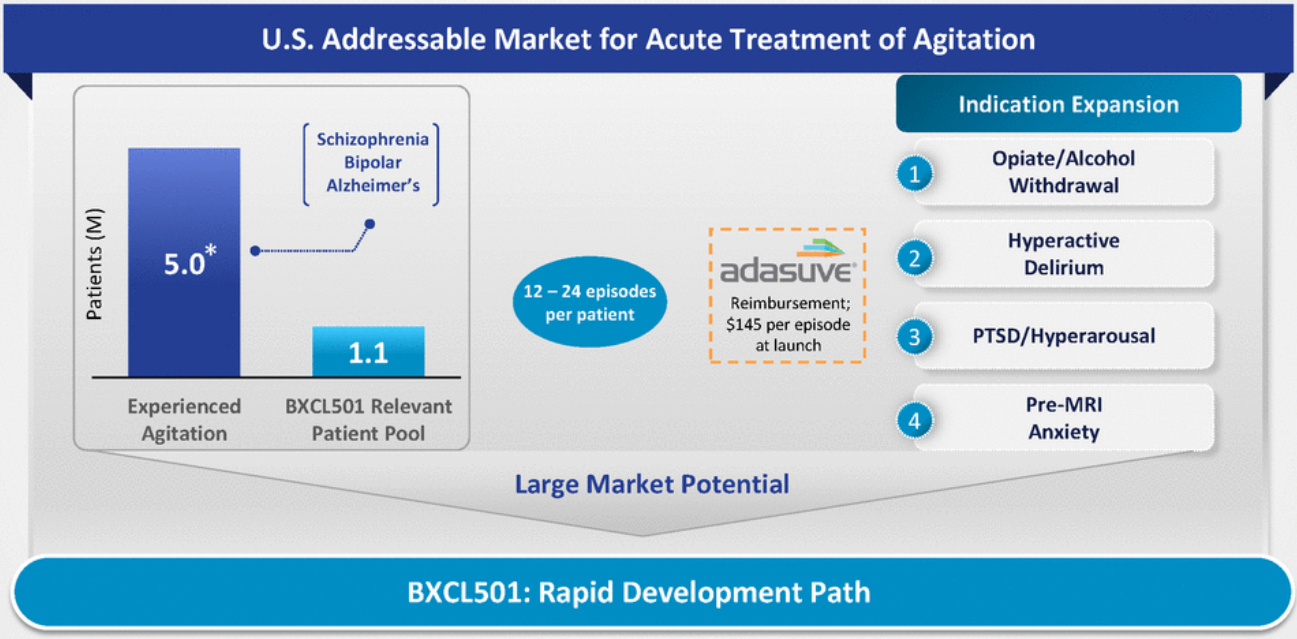
adasuve (loxapine) inhalation powder

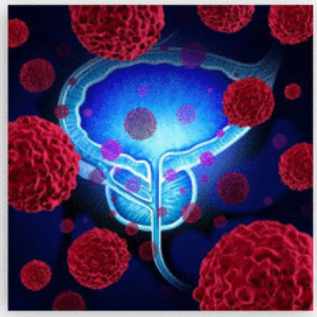
[IND]
2018
2019
2020
[First NDA Submission]

*Clinical Development plan subject to agreement with FDA

Healthcare Costs Associated with Agitation are a Significant Economic Burden

Cost of acute agitation treatment across neuroscience disorders





Clinical Programs

***BXCL701**: First-in-Class Oral IO Therapy Targeting Pancreatic Cancer and tNEPC*

BXCL701: Potential First-in-Class Oral IO Therapy Targeting Pancreatic Cancer and tNEPC

Rare tumors with large market opportunity and limited competition

Orally Administered Activator of Systemic Innate Immunity Pathway

Dual MoA Inhibits DPP 8/9 & FAP

Established **clinical proof of mechanism** & tolerable safety profile

Clinical Partnership: Pfizer, Merck, Nektar

FDA Orphan Drug Designation

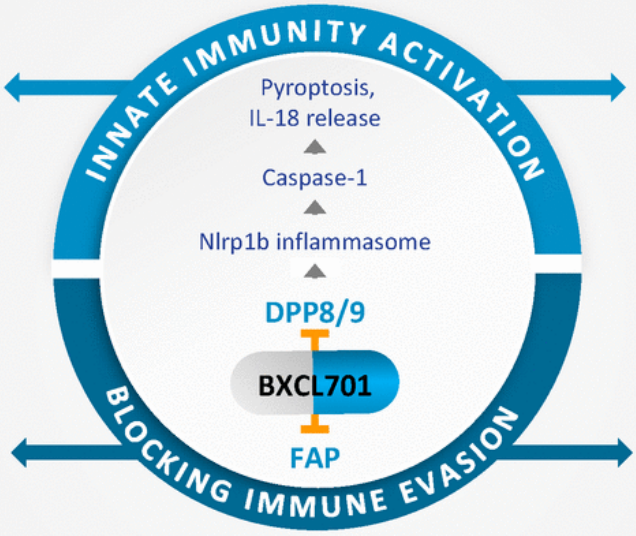
nature chemical biology — Validation of AI Approach[1]

(1) *Nature Chemical Biology*, volume 13, pages 46–53 (2017)

BXCL701 Mechanism of Action

With overlapping factors and effects

Activation of cytotoxic T and NK cells



Cytokine Release, IL18, IL-1β, IL-8, MCP1, GCSF, IL-5, IL-6

Depletion of CAF, MDSCs, immature dendritic, Treg cells

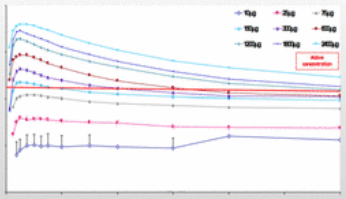
Breaks Fibrotic barrier

Complete Regression of Tumors Observed in Multiple Models with BXCL701 + NKTR-214 + Anti-PD-1 & Formation of Immunological Memory

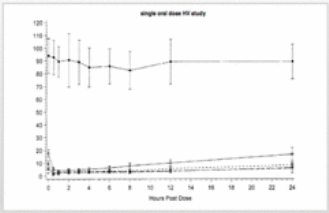
BXCL701: Existing Clinical Evidence Enables Rapid Development Path

Data from >700 patients demonstrate well characterized PK/PD, target inhibition, & anti-tumor activity

✓ Dose



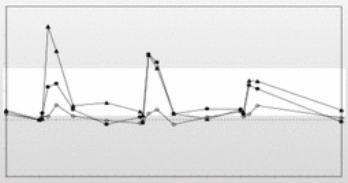
✓ Target Inhibition



BXCL701 Human Proof of Concept

- ✓ Single Agent Efficacy
- ✓ ~10% CR/PR Long Duration
- ✓ Comparable to Yervoy (anti-CTL4)

More than $75 million investment (Point Therapeutics)



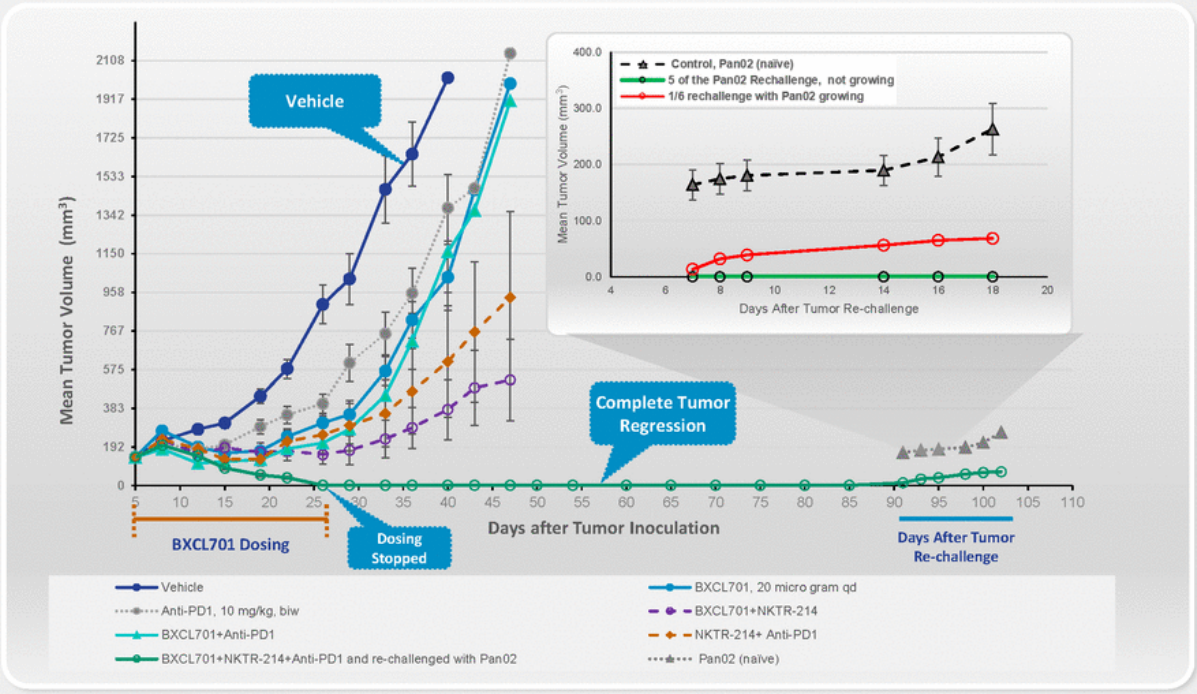
✓ Stimulation Of Immune Cells

✓ Induction of Pro-inflammatory Cytokine

----Daily BXCL701 Dose----				
Cytokine[b]	400mg (n=11)	600mg (n=3)	800mg (n=6)	All Talabostat (N=20)
G-CSF	7 (64)	3 (100)	5 (83)	15 (75)
IL-1α	1 (9)	0	0	1 (5)
IL-1β	5 (46)	2 (67)	5 (83)	12 (60)
IL-2	6 (55)	2 (67)	1 (17)	9 (45)
IL-6	5 (46)	2 (67)	4 (67)	11 (55)
IL-8	5 (46)	3 (100)	2 (33)	10 (50)
IL-10	4 (36)	3 (100)	5 (83)	12 (60)
TNF-α	6 (55)	2 (67)	4 (67)	12 (60)
IFN-α	2 (18)	2 (67)	1 (17)	5 (25)

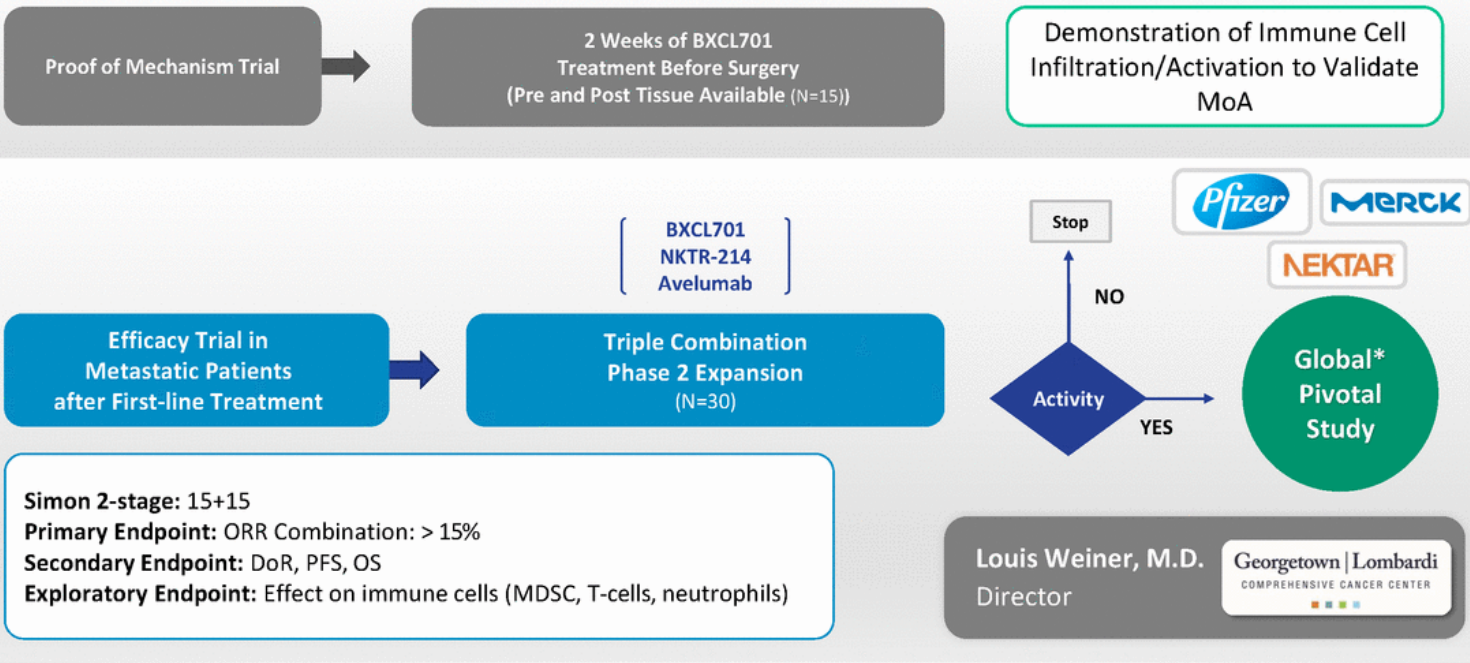
Triple Combination Achieved Complete Regression and Immunity in Pancreatic Tumors

BXCL701 combination with NKTR-214 and Anti-PD-1



Pancreatic Cancer Clinical Development Plan: Mechanistic and Anti-PD1 Combo Trial

Biomarker driven development in advanced pancreatic cancer, potential breakthrough designation



tNEPC Clinical Development Plan: BXCL701 Combination with Keytruda

Biomarker driven development, breakthrough and fast track designation potential

Safety Run-in
Safety/PD/Immune-phenotyping
(N=6)

→

Phase 2 Expansion
(N=30)

→

Global* Pivotal Study

*Expect to commence global development planning during Phase 2

Focus on EU and Japan

KEYTRUDA® (pembrolizumab)

✓ **Patient Recruitment Ongoing**

Simon 2-stage: 15+15
Primary Endpoint: ORR Combination: increase from ~3-5% (Keytruda single agent) to > 15%
Secondary Endpoint: DoR, PFS, OS
Exploratory Endpoint: Effect on immune cells (MDSC, T-cells, neutrophils)

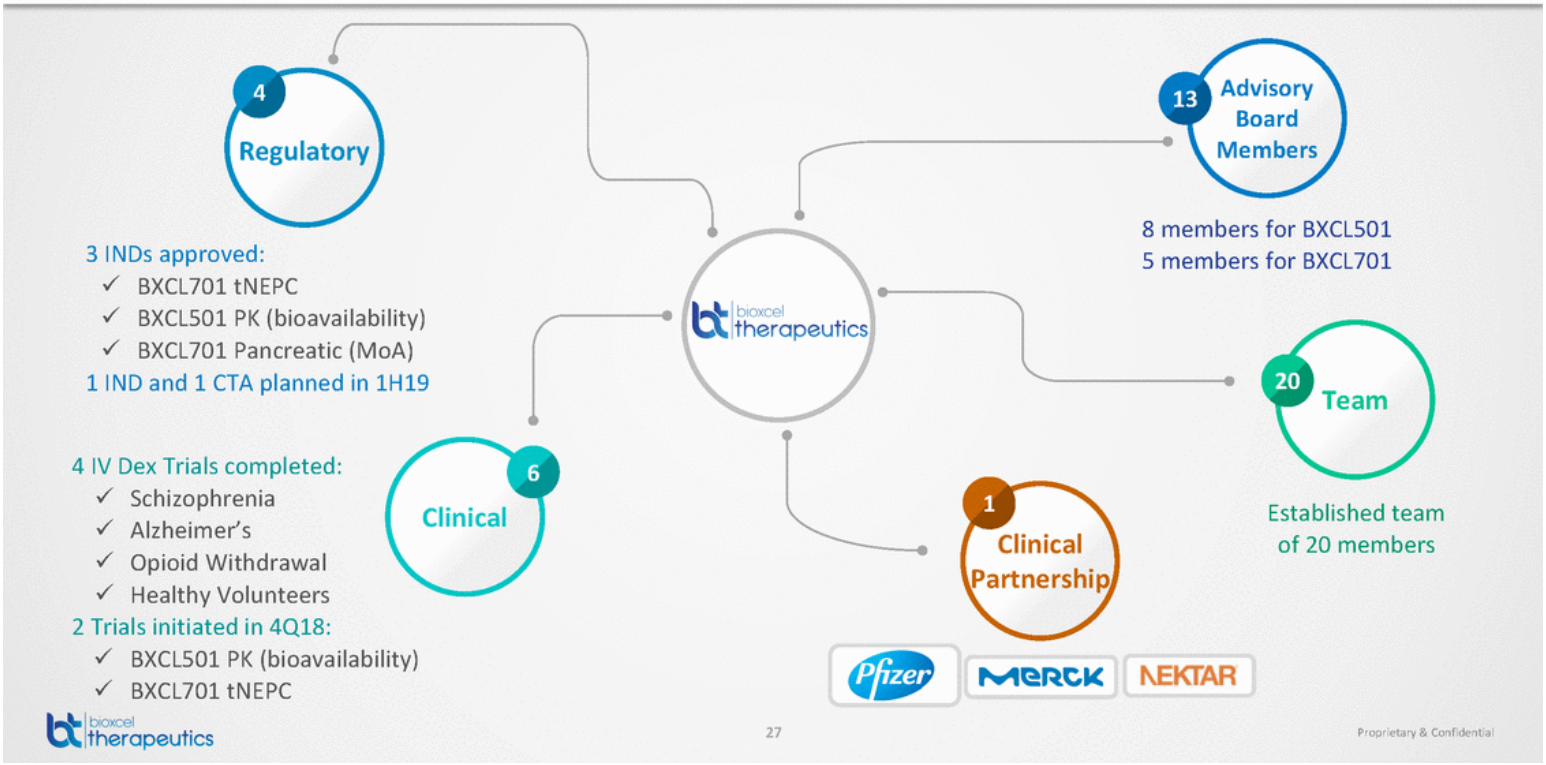
Eric Small, M.D.
Chief, Division of Hematology/Oncology

UCSF Health

Value Creation Catalysts

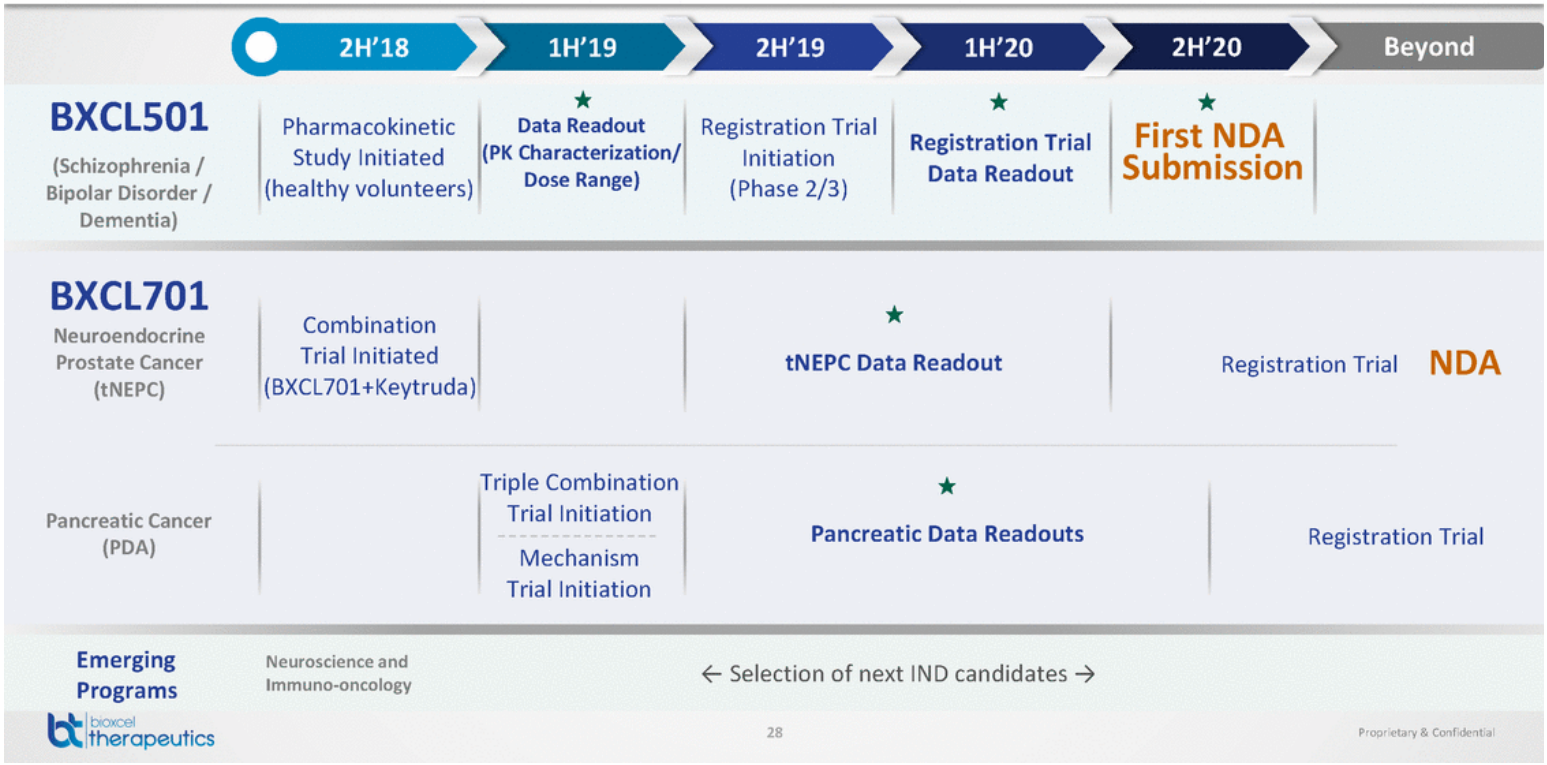
Milestones Accomplished Since IPO

Highlights as of 1Q19



Key Milestones for Value Creation

Two mid-stage clinical trial candidates



Optimally Positioned for Execution

Support from world-class investors

Funded to Reach Multiple Inflection Points

Total Cash and Cash Equivalents:	**42.6 million** as of December 31st, 2018
Major Shareholders:	**Artemis (7.4%)*** **Fidelity (5.5%)*** **DNCA Finance (5.11%)**
Analyst Coverage:	Geoff Meacham (**Barclays**) Carter Gould (**UBS**) Do Kim (**BMO Capital Markets**) Sumant Kulkarni (**Canaccord Genuity**) Ram Selvaraju (**H.C. Wainwright**)

ARTEMIS The PROFIT Hunter

Fidelity INVESTMENTS

DNCA INVESTMENTS

* As of February 2019

Appendix

Management Team

Board Profile

World-Class Leadership Team Supported By Strong Board of Directors and Advisory Board

Combined experience of 150+ years in drug development with 15 approved drugs

MANAGEMENT TEAM

VIMAL MEHTA

CEO & Member of Board

- BioXcel
- inpharmatica
- CURAGEN

FRANK YOCCA

Chief Scientific Officer

- AstraZeneca
- Bristol-Myers Squibb

VINCENT J. O'NEILL

Chief Medical Officer

- Genentech
- gsk GlaxoSmithKline
- sanofi aventis

RICHARD I. STEINHART

Chief Financial Officer

- remedy PHARMACEUTICALS
- MELA Sciences

World-Class Leadership Team Supported By Strong Board of Directors and Advisory Board

Combined experience of 150+ years in drug development with 15 approved drugs

BOARD OF DIRECTORS

PETER MUELLER

Chairman of Board

VERTEX

Boehringer Ingelheim

The Mueller Health Foundation

STEVE LAUMAS

Member of Board

Goldman Sachs

INNOVATE Biopharmaceuticals

KRISHNAN NANDABALAN

Member of Board

BioXcel

GENAISSANCE PHARMACEUTICALS

CURAGEN

STRATEGIC ADVISORS

STEVEN PAUL

Member of Board, Voyager Therapeutics

Lilly

SAGE THERAPEUTICS

Voyager THERAPEUTICS

SHEILA GUJRATHI

CEO, Gossamer Bio

Genentech

Bristol-Myers Squibb

gossamerbio

Neuroscience Clinical Advisory Board to Support Global Development of BXCL501

Prominent clinicians and neuroscientists to guide advancement of lead programs and emerging neuroscience pipeline

Clinical Advisory Board

Sheldon H. Preskorn, M.D.
Professor of Psychiatry

KU School of Medicine Wichita – The University of Kansas

Stephen R. Marder, M.D.
Director, Section on Psychosis

Semel Institute UCLA

George Grossberg, M.D.
Director, Geriatric Psychiatry

Saint Louis University School of Medicine

Alan Breier, M.D.
Professor of Psychiatry,
Vice-Chair for Clinical Research

Indiana University School of Medicine

John Krystal, M.D.
Chair,
Department of Psychiatry

Yale NewHaven Health

Maurizio Fava, M.D.
Director,
Division of Clinical Research

MGH 1811

Thomas Laughren, M.D.
Director,
Regulatory Affairs

MGH 1811

Thomas Kosten, M.D.
Director, Division of Alcohol and
Addiction Psychiatry

Baylor College of Medicine

Immuno-Oncology Clinical Advisory Board to Advance BXCL701 Development

Appointment of world renowned immuno-oncology clinicians and scientists

Clinical Advisory Board

Louis M. Weiner, M.D.

Director, Georgetown Lombardi Comprehensive Cancer Center

Georgetown | Lombardi COMPREHENSIVE CANCER CENTER

NIH NATIONAL CANCER INSTITUTE

Daniel Von Hoff, M.D., F.A.C.P.

Physician in Chief, Distinguished Professor at the TGen

tgen AN AFFILIATE OF City of Hope

Abraxane®

Eric J. Small, M.D.

Chief, Division of Hematology/Oncology

UCSF Health

Zytiga®

Emmanuel S. Antonarakis, M.D.

Associate Professor of Oncology and Urology

JOHNS HOPKINS MEDICINE THE SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER

KEYTRUDA®

Johann de Bono, M.D., Ph.D.

Head, Division of Clinical Studies

ICR The Institute of Cancer Research

Xtandi®

Dr. Vimal Mehta, CEO

BioXcel Therapeutics, New Haven, CT 06511

vmehta@bioxceltherapeutics.com