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)
December 12, 2018

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38410**	**82-1386754**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I. R. S. Employer Identification No.)

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.

BioXcel Therapeutics, Inc. (the "Company") has prepared presentation materials (the "Presentation Materials") that management intends to use from time to time on and after December 12, 2018, in presentations about the Company's operations and performance, The Company may use the Presentation Materials in presentations to current and potential investors, lenders, creditors, insurers, vendors, customers, employees and others with an interest in the Company and its business.. The Presentation Materials are furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	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: December 12, 2018

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1


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

Safe Harbor Statement

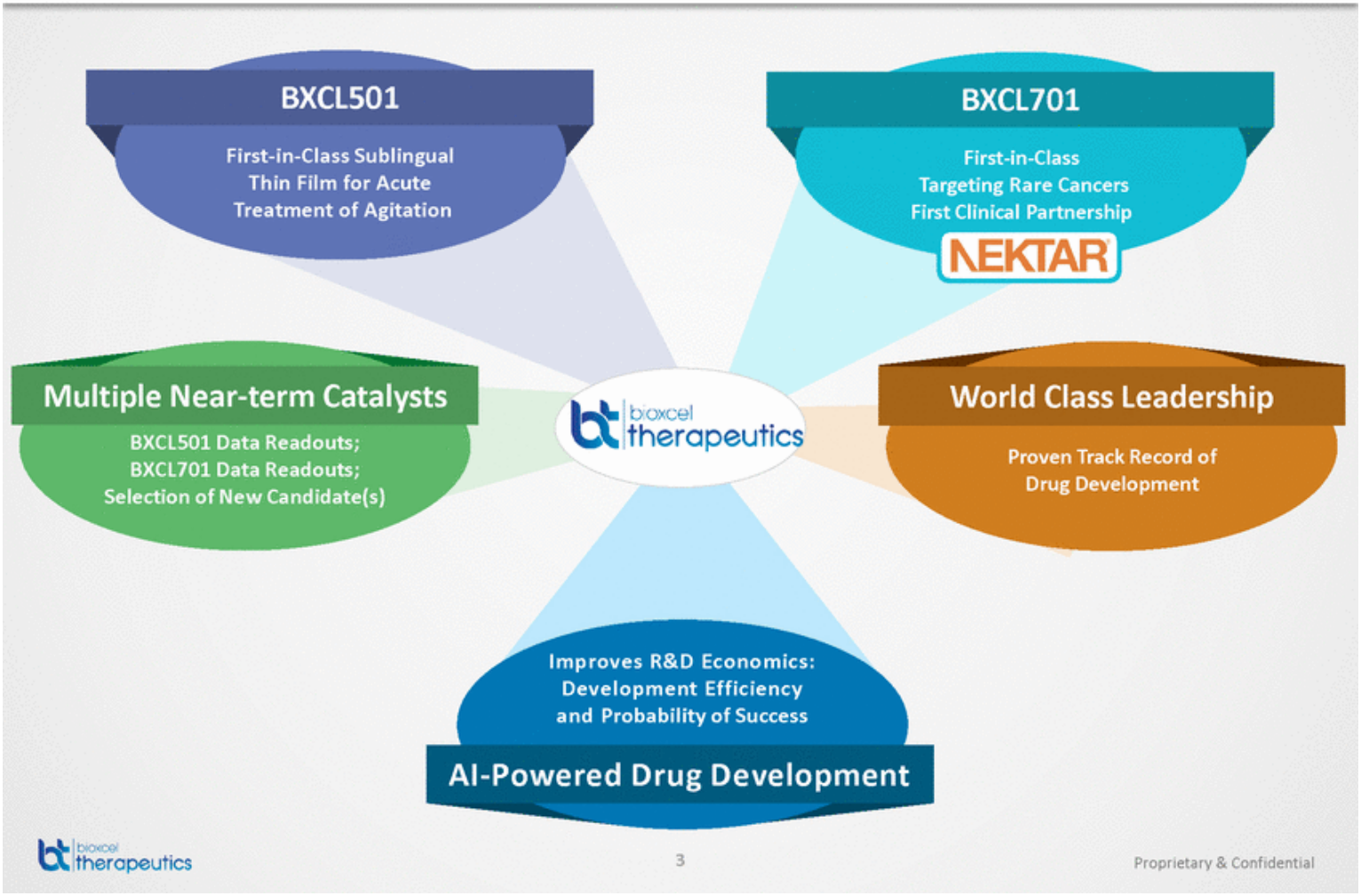
This document may contain forward-looking statements. Such forward-looking statements are characterized by future or conditional verbs such as "may," "will," "expect," "intend," "anticipate," believe," "estimate" and "continue" or similar words. You should read statements that contain these words carefully 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.

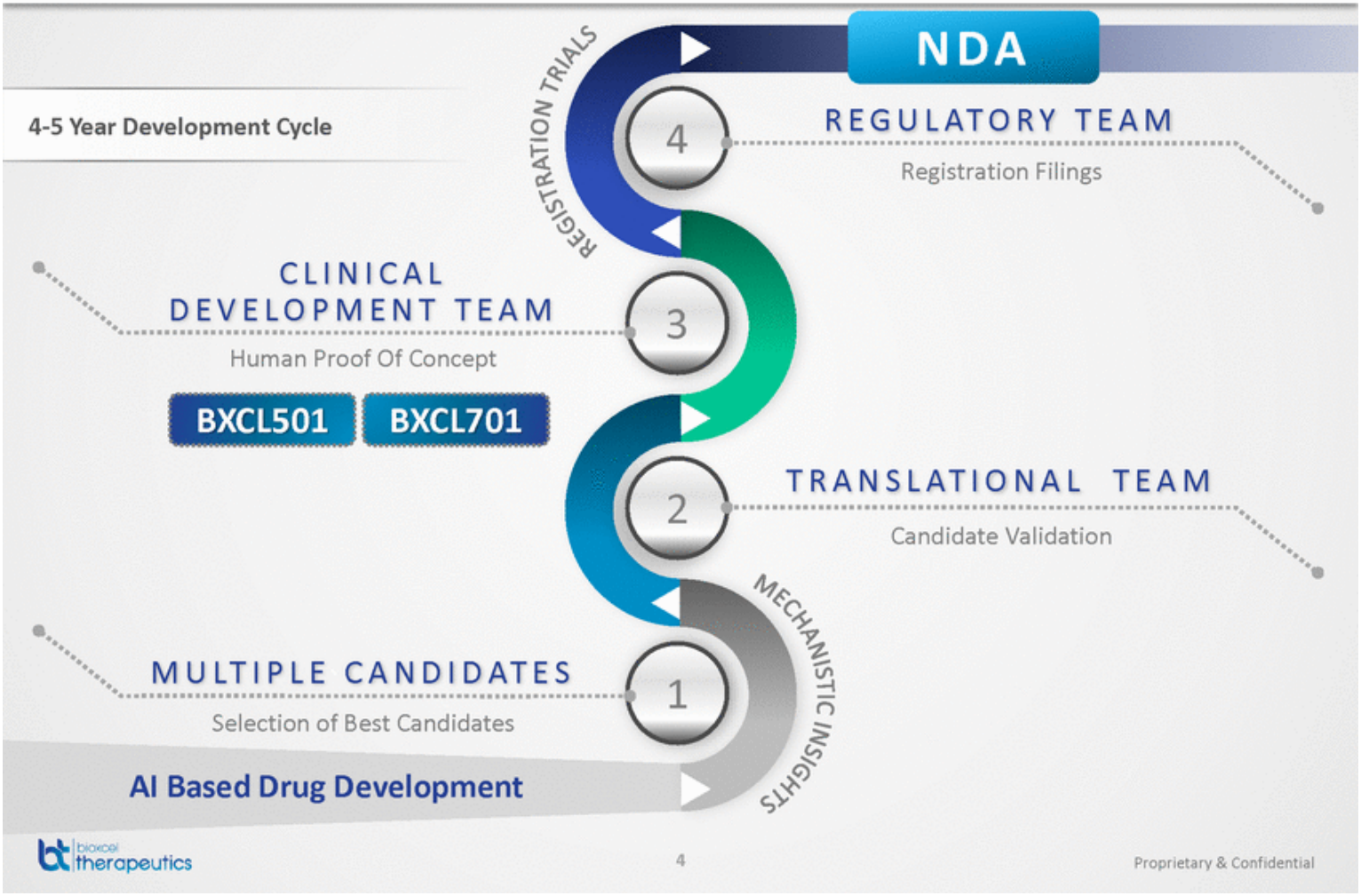
BioXcel Therapeutics Investment Highlights

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



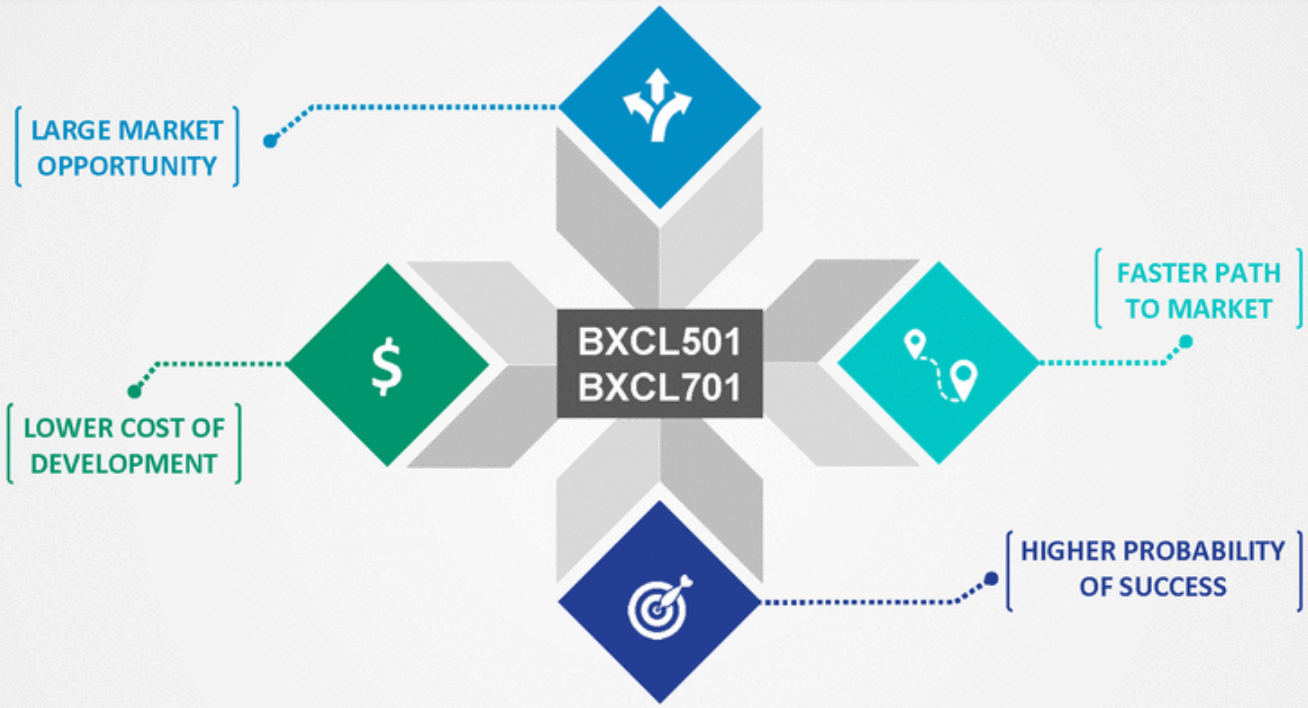
BTI is Unleashing the Power of AI Across the Entire R&D Value Chain

Opportunity to generate multiple NDAs



Attractive Portfolio Features

De-risked approach

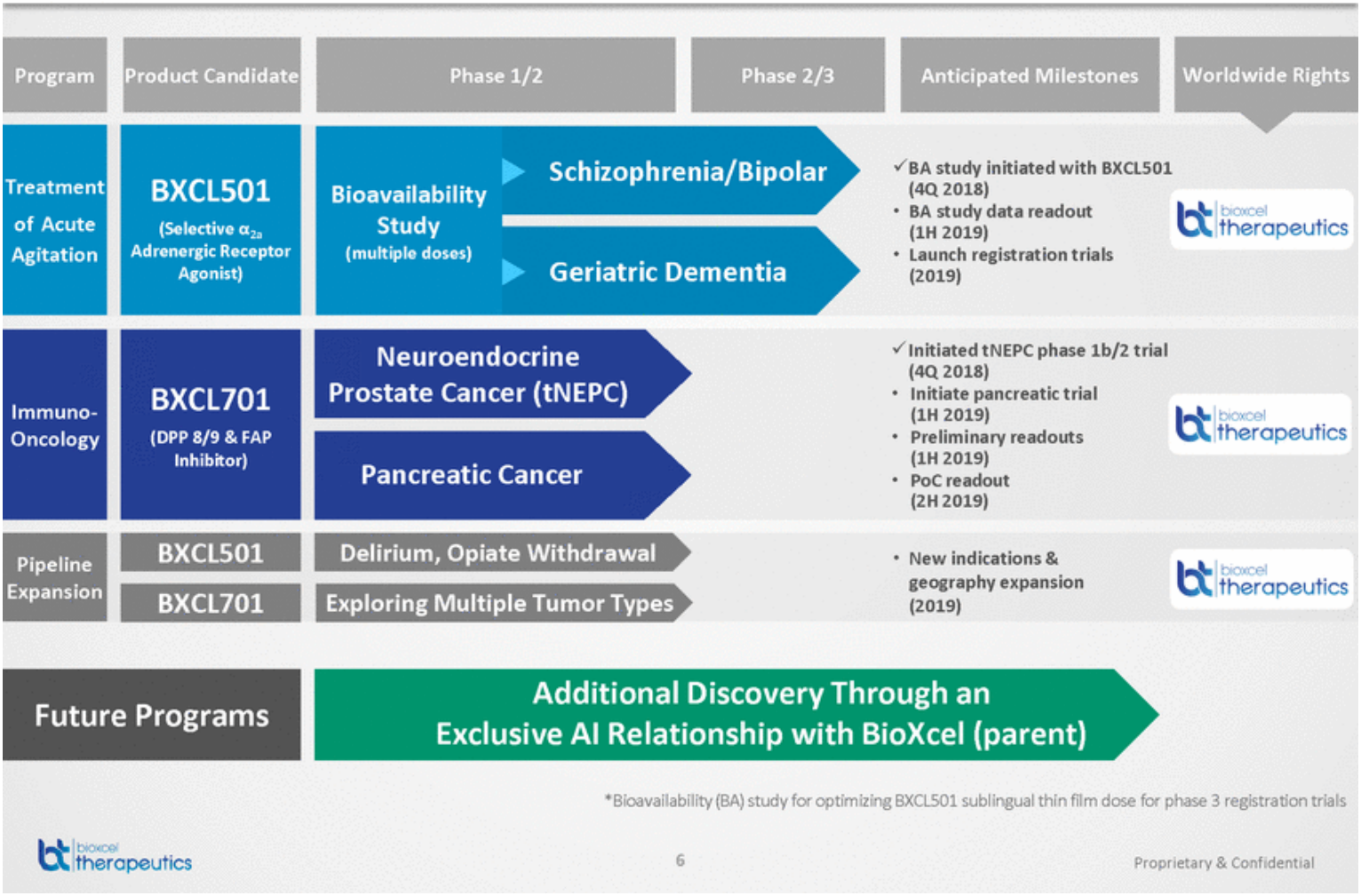


KEY FEATURES TO LAUNCH PROGRAM

Target Engagement → CMC → Clinical Proof of Mechanism → Clinical PK/PD → Clinical Safety → Regulatory Path

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*

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

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

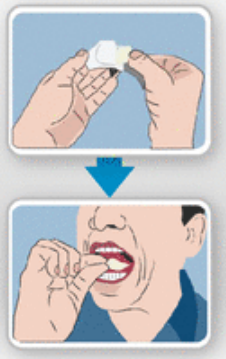
- Agitation: a growing **global healthcare issue ($40B+)**
- Existing treatments are **invasive** with **severe side effects**
- BXCL501 - an **innovative approach:**
  - *Directly targets a **causal agitation mechanism***
  - *Easy to administer **sublingual film** with **rapid onset of action***
  - *Established **regulatory and reimbursement path (Adasuve)***

BXCL501: Sublingual Thin Film Formulation of Dexmedetomidine (Dex)

Sublingual film formulation under development with multiple dose strengths

Ideal Pharmaceutical Properties for a Non-invasive Sublingual Film Formulation

- Film **manufacturing completed**: drug **available for clinical studies**
- **Immediate release** type film with **muco-adhesion** properties
- **Multiple dose strengths** ranging from **10 µg to 60 µg** for initial clinical studies
- Developed using **proprietary technology** to handle **low dose ranges**



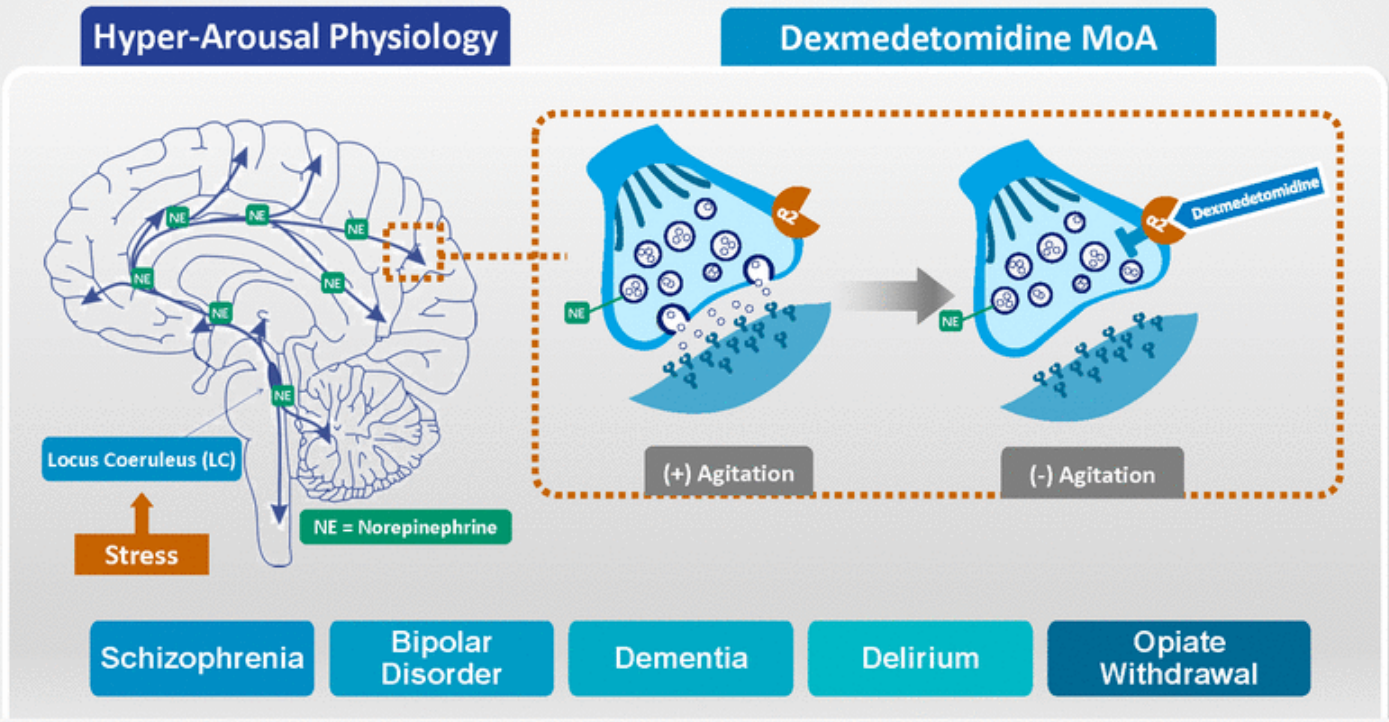
The Right Pharmacology and Safety Profile (Precedex – IV Dex)

- Initially Developed by Hospira as anesthetic/sedative (1999)
- Prescribed to **8M+ patients**
- Studied in **120 clinical trials**
- Demonstrated **efficacy in managing agitation** from **schizophrenia & delirium**

Effective Dose	Sedative Dose	Tolerable Dose
0.5µg/kg	*1.6µg/kg*	*>5µg/kg*

Dexmedetomidine Mechanism of Action

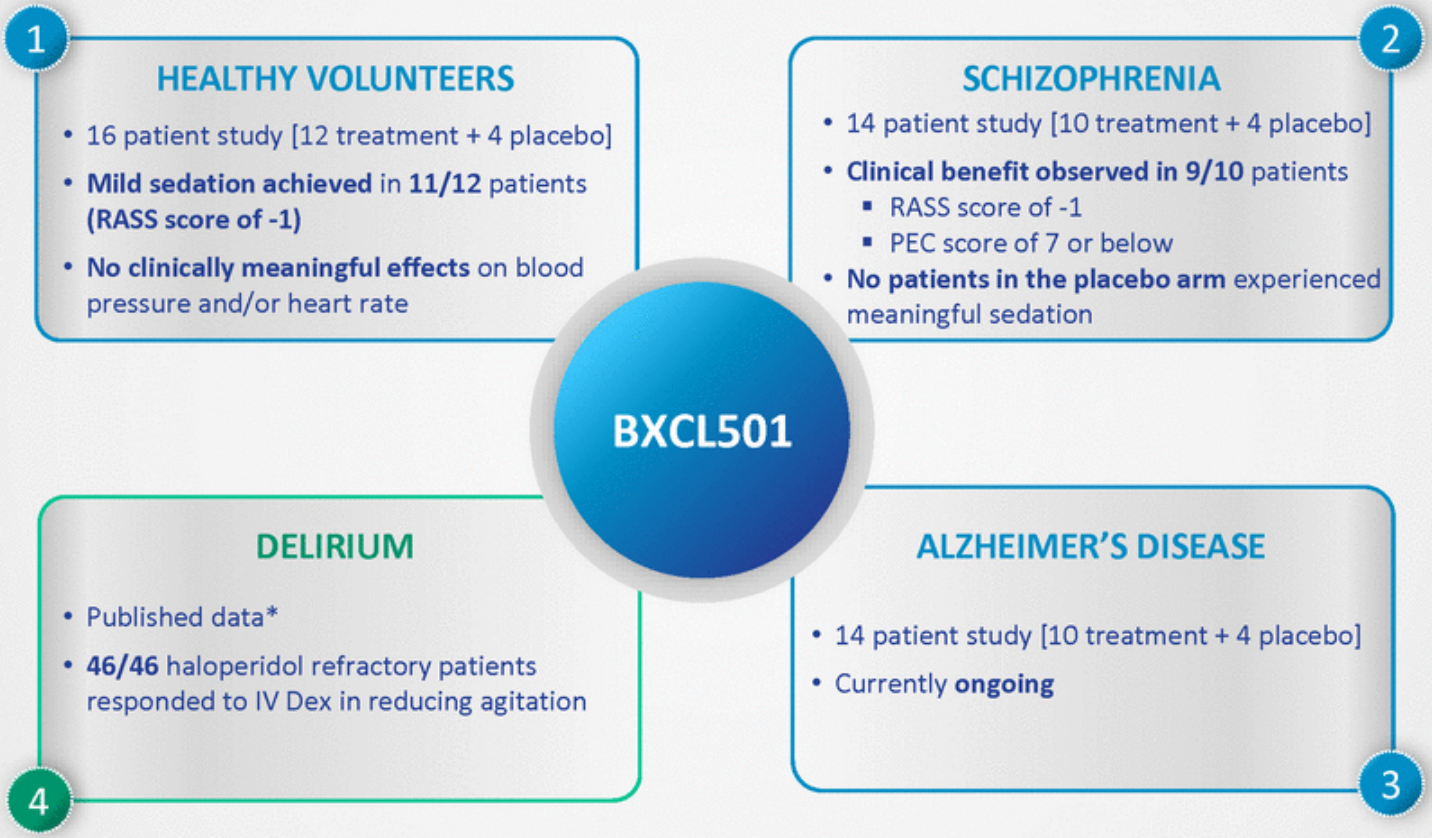
Reduction of hyper-arousal from overactive locus coeruleus neurons in response to stress



- Presynaptic α2 adrenergic receptors hyperpolarize LC neurons and prevent the release of NE.
- Dexmedetomidine (α2 adrenergic agonist) effectively shuts down LC neurons and reduces agitation with minimal sedation by reducing NE outflow.

BXCL501 Human Proof of Concept

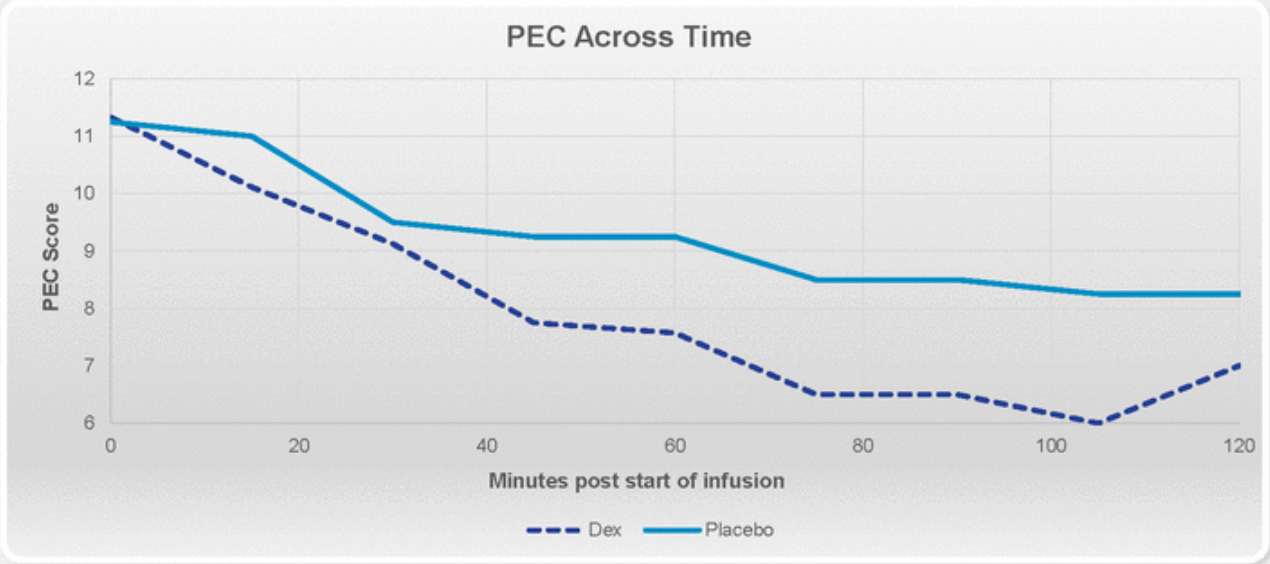
IV Dex data from 90 patients: healthy volunteers and three disease pathologies



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

Positive Results from IV Dex Study in Agitated Schizophrenia Patients

Study results announced Nov 2018: primary endpoint met



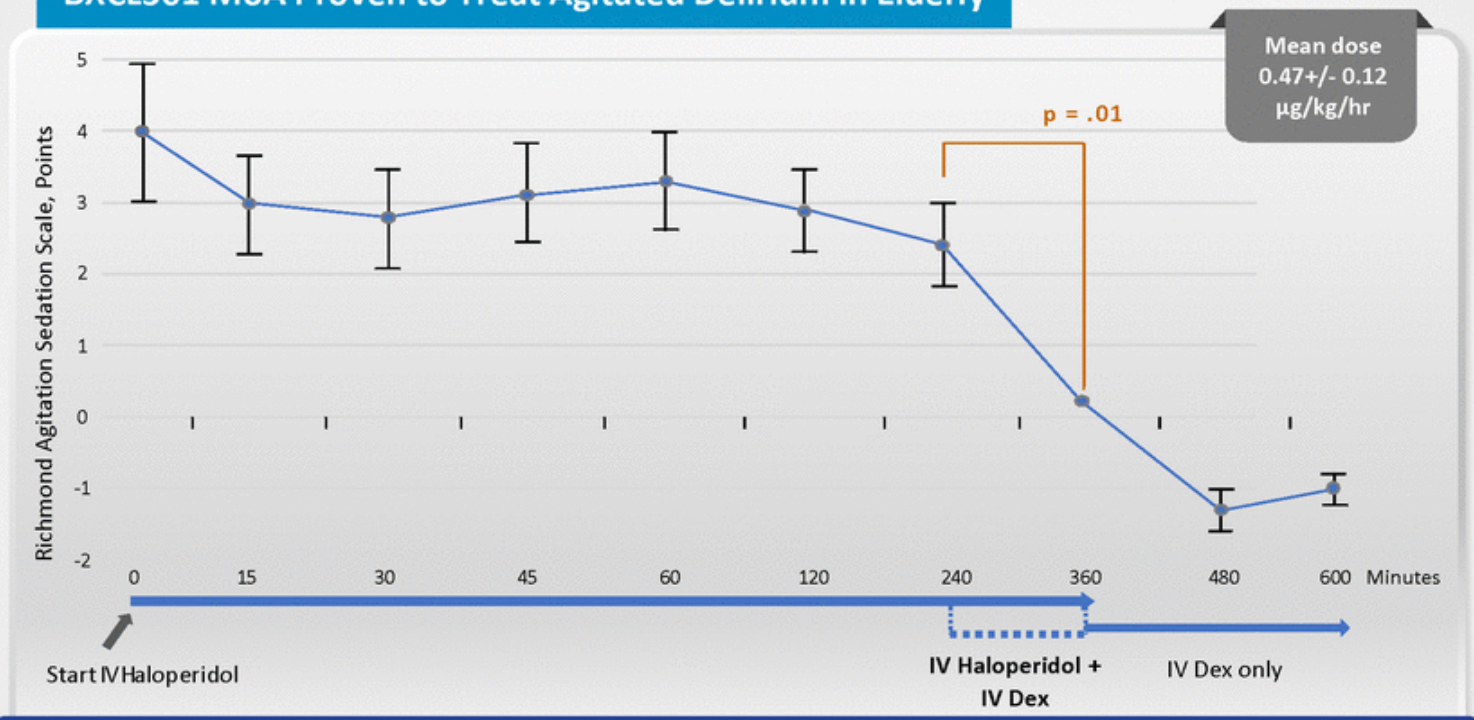
Key Findings

- Small (n=14) randomized, placebo-controlled dose-ranging study, not powered to demonstrate statistical differences.
- **9 of 10 treated** patients achieved a **RASS score of -1** (arousable sedation).
- **9 of 10 treated** patients had a **PEC score of 7 or below** (maximal agitation reduction).
- The reduction in agitation occurred before achieving sedation, demonstrating an **increased therapeutic index of the drug**.
- There were **no clinically relevant cardiovascular changes**.

Acute Agitation Clinical Study Shows Easily Measured Endpoints

Hyperactive delirium patients refractory to haloperidol are difficult to treat

BXCL501 MoA Proven to Treat Agitated Delirium in Elderly

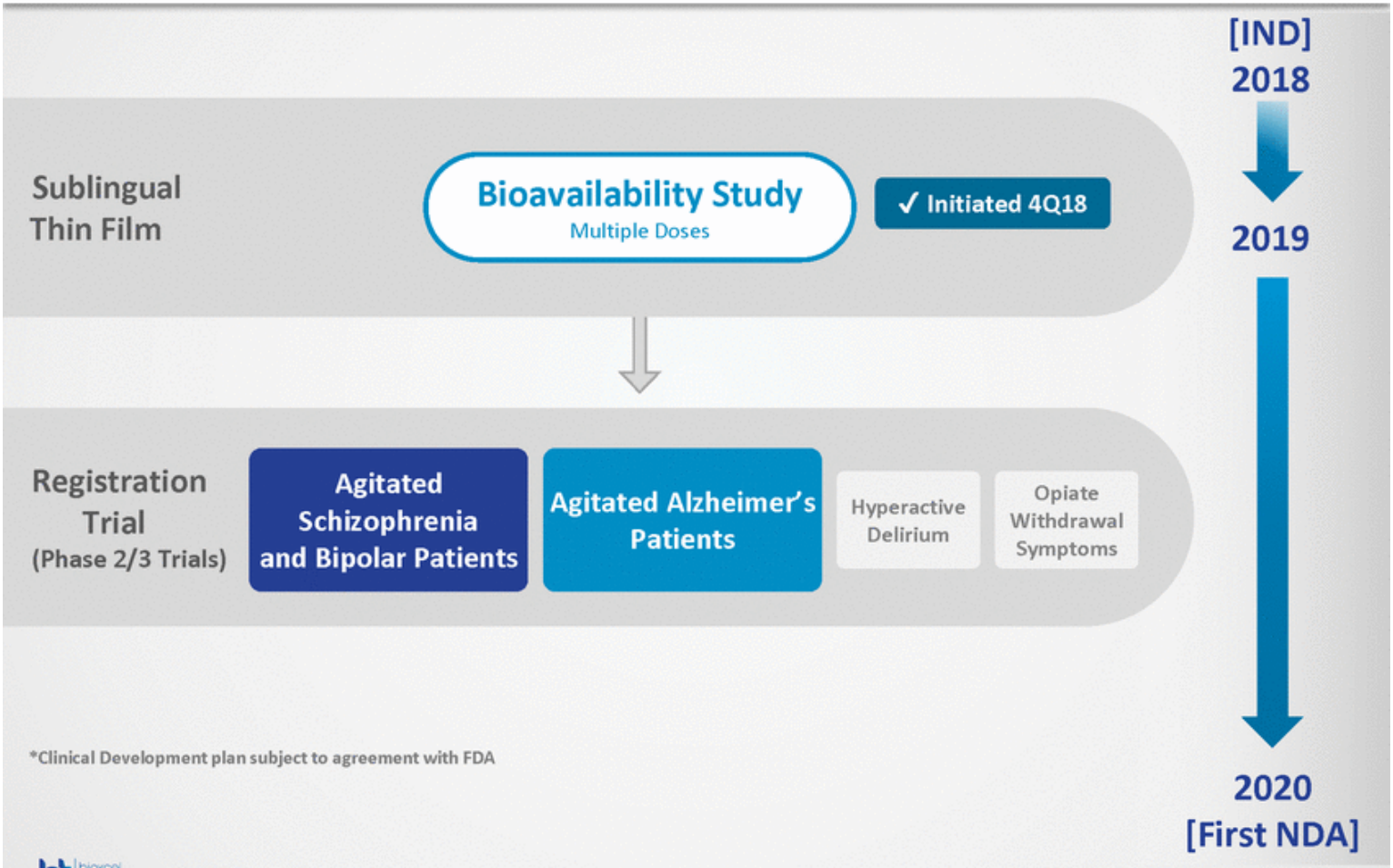


All Haloperidol-refractory Agitated Patients (n=46) were Calmed by Dex Treatment

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

BXCL501 Integrated Clinical Development Plan

Acute agitation studies: short with easily measurable clinical endpoints

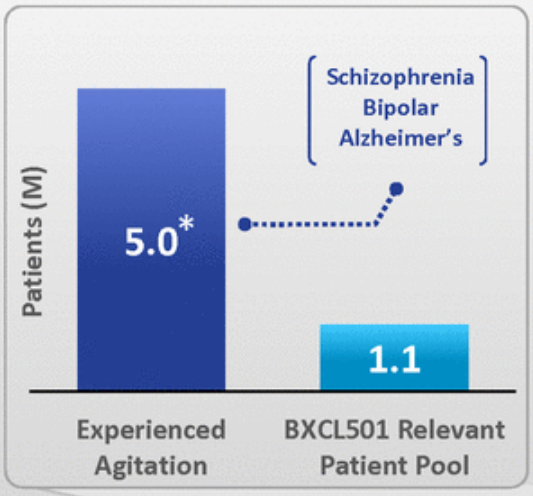


*Clinical Development plan subject to agreement with FDA

Healthcare Costs Associated with Agitation are a Significant Economic Burden

Cost of acute agitation treatment across neuroscience disorders

U.S. Addressable Market for Acute Treatment of Agitation



12 – 24 episodes per patient

adasuve®

Reimbursement; $145 per episode at launch

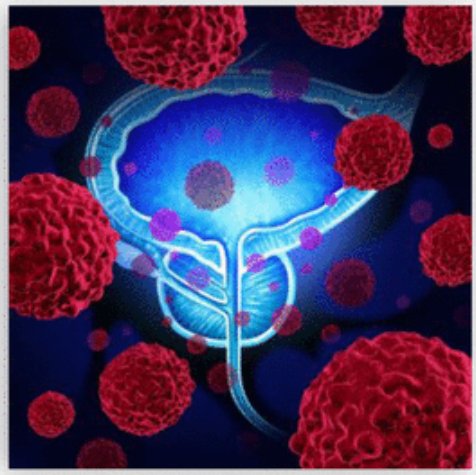
Indication Expansion

- Hyperactive Delirium
- Opiate/Alcohol Withdrawal
- PTSD/Hyperarousal
- Pre-MRI Anxiety

Large Market Potential

BXCL501: Rapid Development Path

* Alzheimer's and Schizophrenic / Bipolar patients



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
  - Converts **"cold" tumors to "hot" tumors**
  - Differentiated **dual MoA** inhibits **DPP 8/9 & FAP**
- Induces **immune-activation** and blocks **immune-evasion**
- Established **clinical proof of mechanism** and **tolerable safety profile**
- Offers **synergistic benefit** with **multiple IO modalities**

Clinical Partnership NEKTAR

FDA Orphan Drug Designation

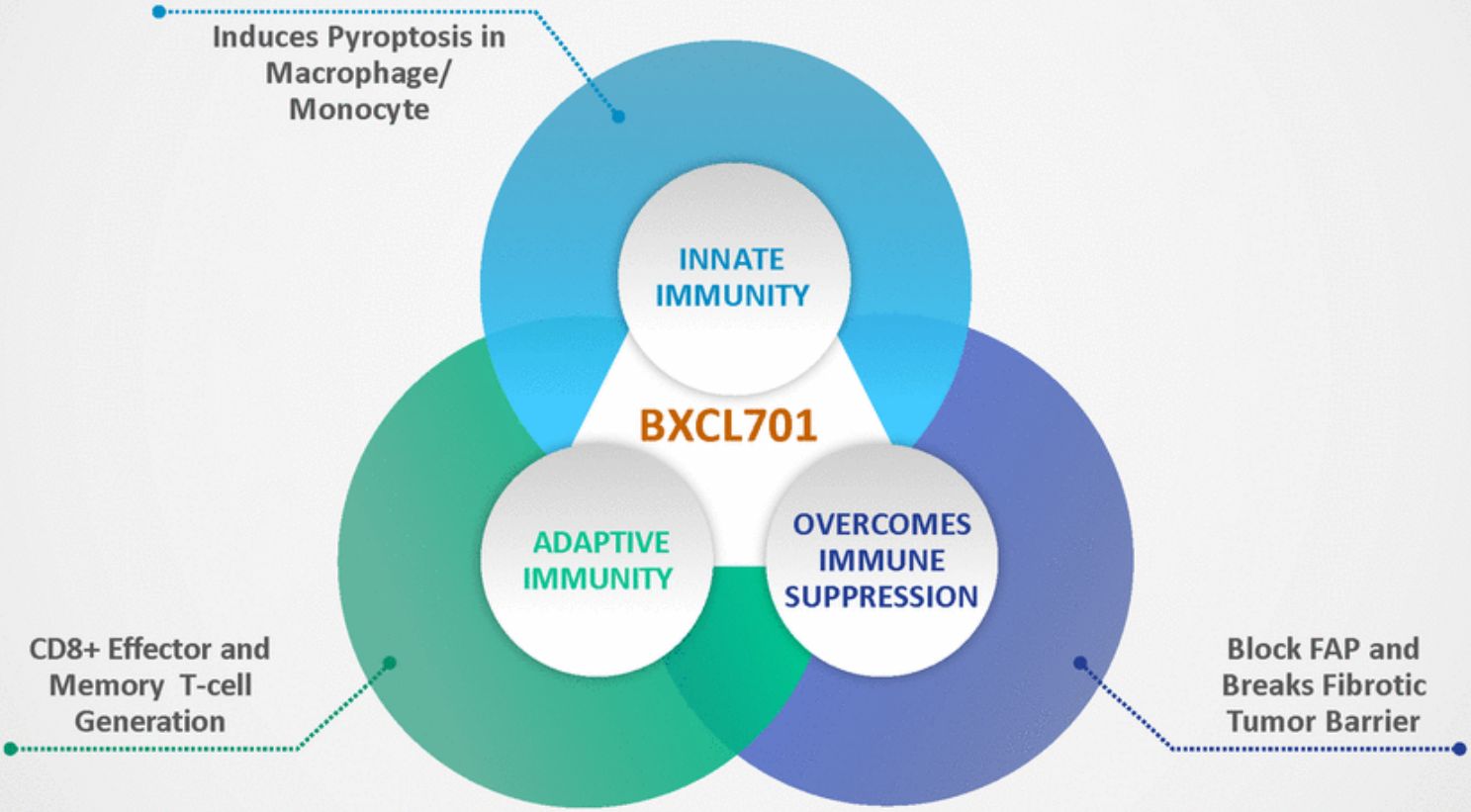
Validation of AI Approach(1)

Potential for **Accelerated Approval** and **Breakthrough Therapy Designations**

(1) http://www.nature.com/nchembio/journal/v13/n1/abs/nchembio.2229.html?foxtrotcallback=true

BXCL701 Affects Tumor Immune Responses at Multiple Levels

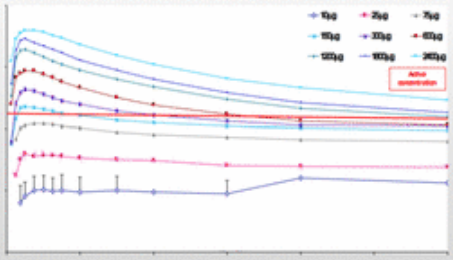
With overlapping factors and effects



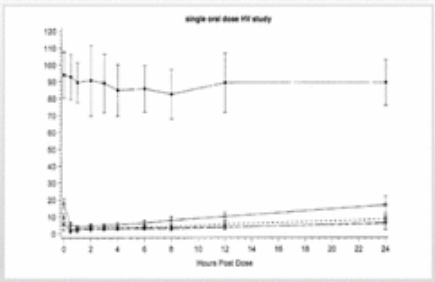
BXCL701: Existing Clinical Evidence Enables Rapid Development Path

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

✓ Dose



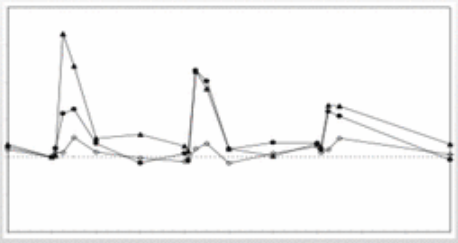
✓ Target Inhibition



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)



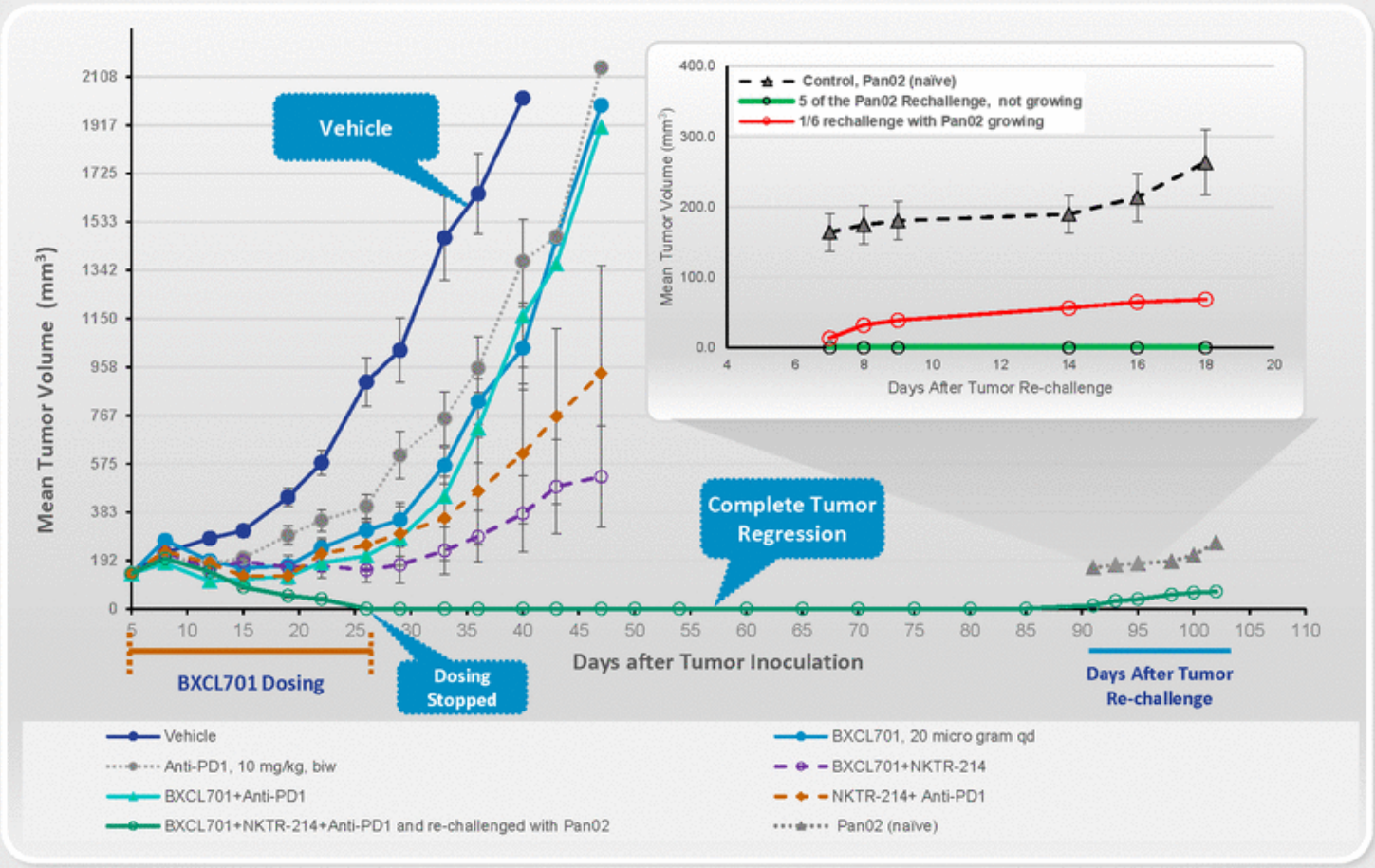
✓ Stimulation Of Immune Cells

✓ Induction of Pro-inflammatory Cytokine

	----Daily BXCL701 Dose----			
Cytokine[a]	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



BTAI and NKTR Clinical Partnership in Pancreatic Cancer

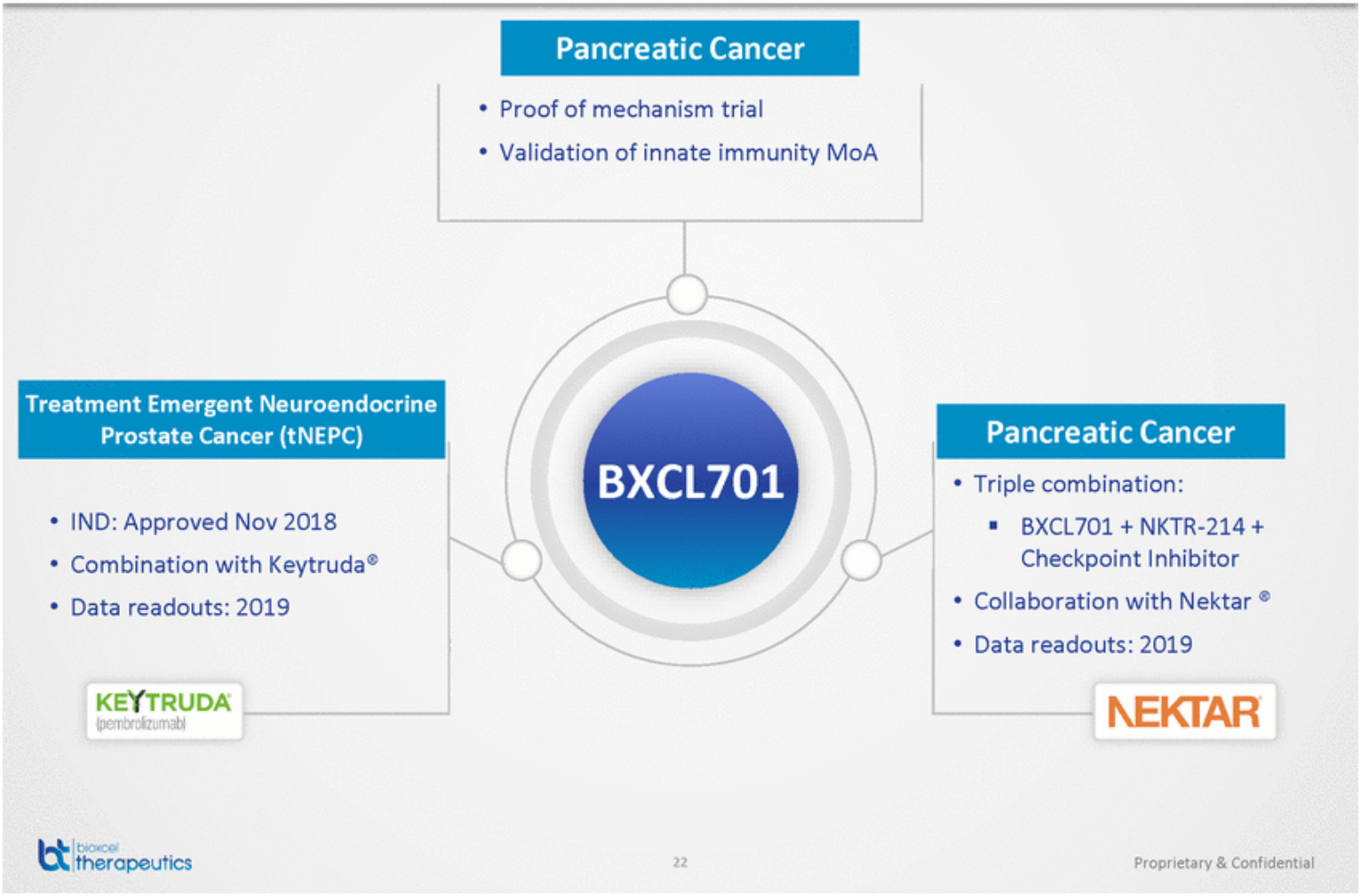
Evaluate triple combination with complimentary mechanisms to achieve durable responses

- Clinical partnership to evaluate novel triple combinations
  - BXCL701, NKTR-214, and a checkpoint inhibitor
- Flexibility to use any checkpoint inhibitor
  - Including anti-PD-1 & anti-PDL-1 antibodies
- Cost of development will be shared between parties
- BTAI will be responsible to conduct the trials
  - Joint Development Committee (JDC) will oversee the study
- Patent rights for the combination shall be jointly owned by the parties

BXCL701 Validation through Clinical Partnership

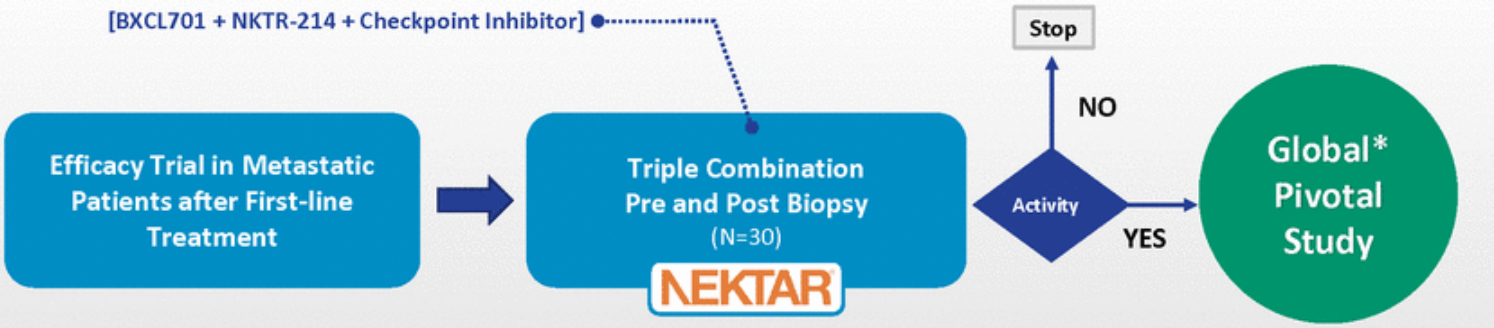
BXCL701 Human Proof of Concept in Two Rare Forms of Tumor

Engaged in three clinical trials



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

Biomarker driven development in advanced pancreatic cancer, potential breakthrough designation



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

Louis Weiner, M.D.
Director

Georgetown | Lombardi
COMPREHENSIVE CANCER CENTER

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)

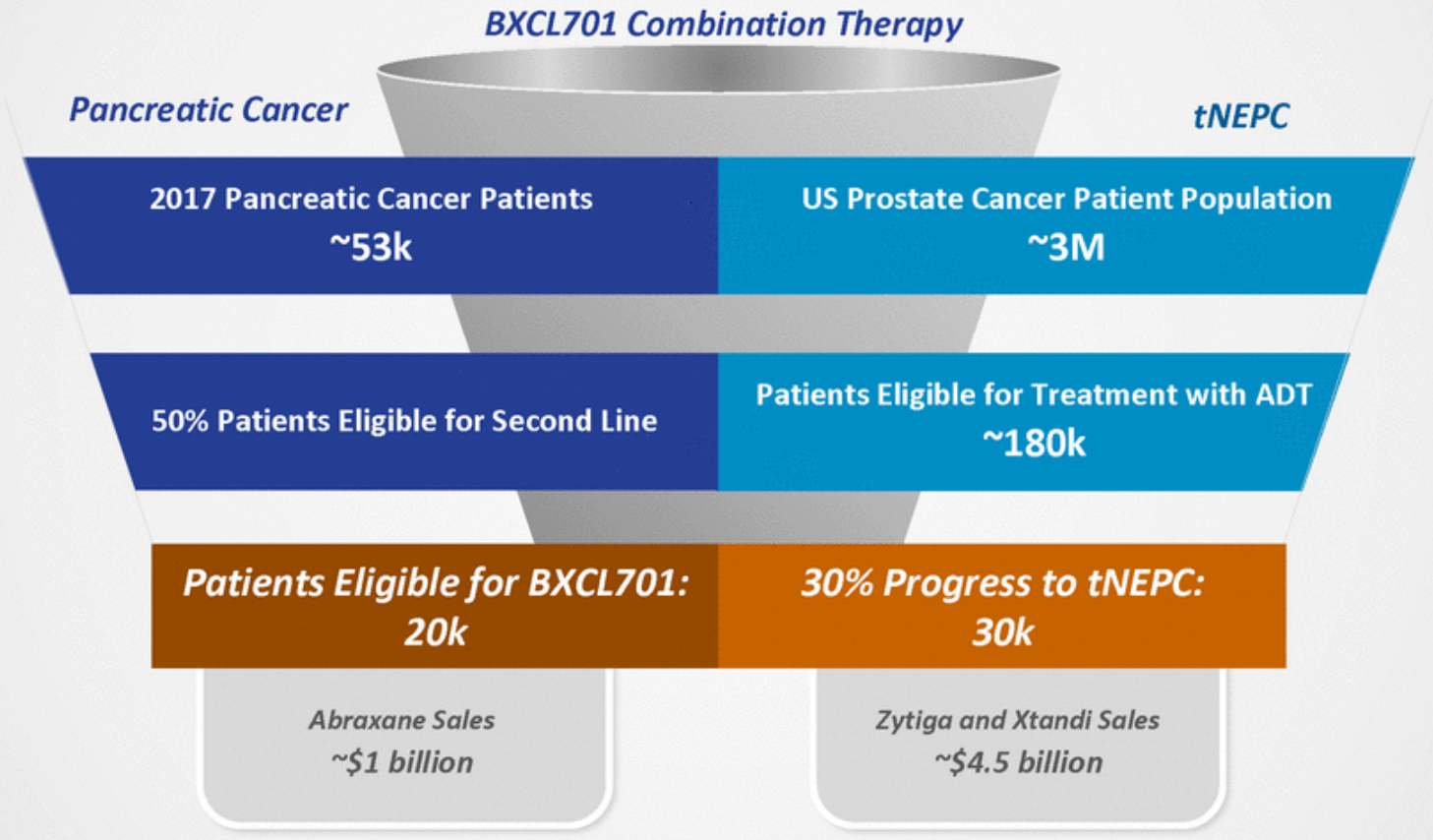
✓ **Trial Initiated: 4Q18**

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

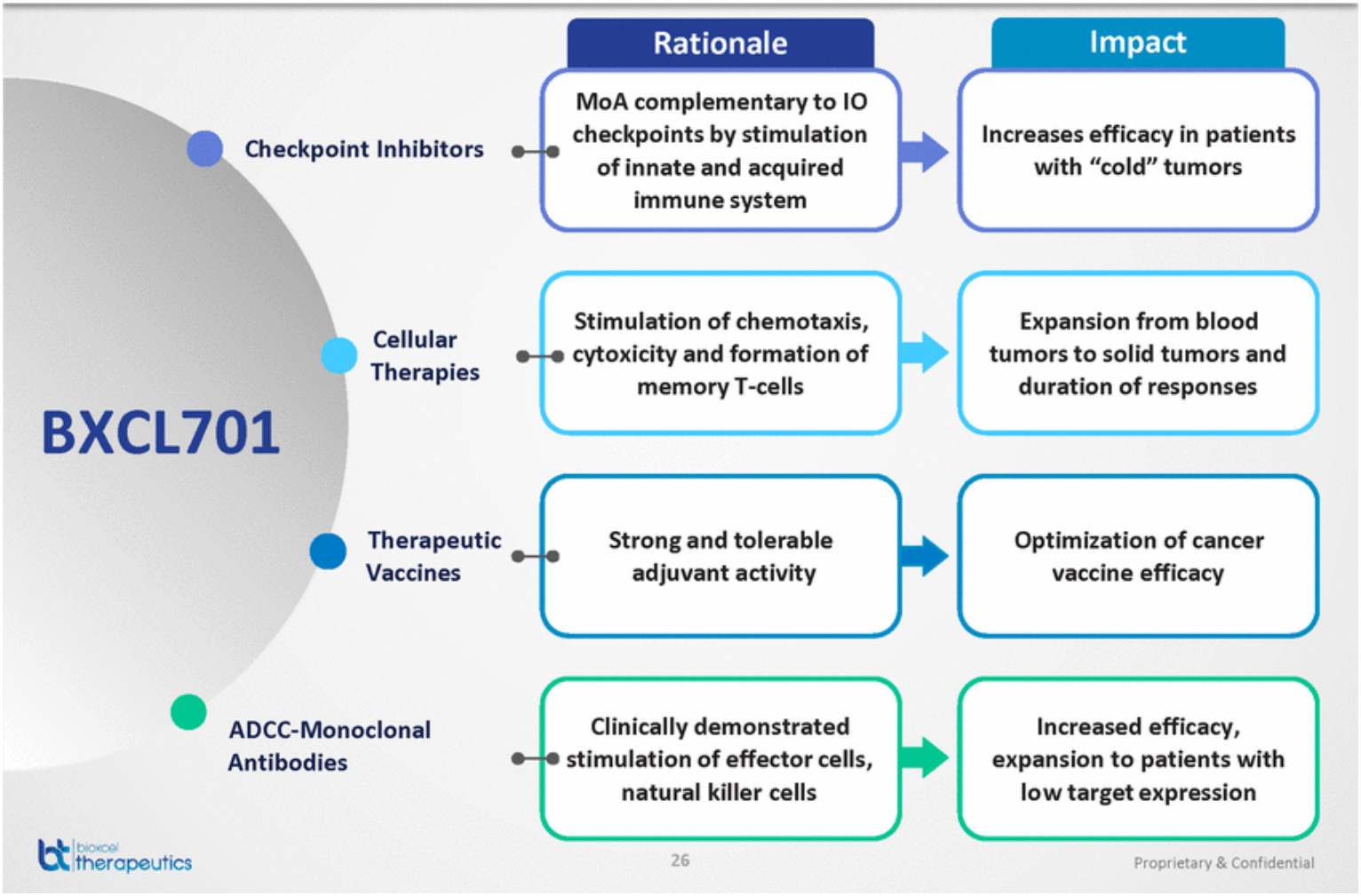
Large Market Opportunity

Limited competition



Offers Pipeline-in-a-Product Platform

Broad potential across multiple IO modalities



Value Creation Catalysts

Milestones Accomplished Since IPO

Highlights from 2018 YTD

BXCL501		BXCL701
Clinical Supplies: ✓	CMC	Clinical Supplies: ✓
IND Accepted Dec 2018	REGULATORY	IND: tNEPC Accepted Nov 2018
Bioavailability Study: 4Q18	CLINICAL	First Patient Dosing in tNEPC: 4Q18
Indication Expansion: Delirium & Opiate Withdrawal	STRATEGIC	Clinical Partnership NEKTAR

Formed World Class 8 Member Advisory Board for BXCL501 & BXCL701
Built a Team of ~20 Members

On Track to **Achieving Key Milestones for Value Creation** in 2018 and 2019

Key Milestones for Value Creation

Two mid-stage clinical trial candidates

Drug	Indication	1H'18	2H'18	1H'19	2H'19	2020 and Beyond	
BXCL501	Healthy Volunteers	IV Dex Study Completed	Bioavailability Study Initiation (Sublingual Thin Film)	Dose Selection		NDA	
	Schizophrenia / Bipolar Disease	IV Dex Study Completed	**Data Announced** / PoC Established	Registration Trial (Phase 2/3)			
	Geriatric Dementia	IV Dex Study Ongoing	**Data Readout** / Further Establish PoC	Registration Trial (Phase 2/3)			
BXCL701	Neuroendocrine Prostate Cancer (tNEPC)		Combination Trial Opened (BXCL701+Keytruda)	**Preliminary Readout**	**Data Readout**	Registration Trial	NDA
	Pancreatic Cancer (PDA)		Proof of Mechanism Trial Initiation (BXCL701)	**Mechanistic Readout**		Registration Trial	
				Triple Combination Trial Initiation	**Data Readout**	Registration Trial	
Emerging Programs	Neuroscience and Immuno-oncology	Selection of Next Candidate(s)					

Optimally Positioned for Execution

Support from world-class investors

Funded to Reach Multiple Inflection Points

- Total cash and cash equivalents of **$47.1 million** as of September 30th, 2018
- Major shareholders include **Fidelity (8.4%), Artemis (8.02%),** and **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**)

Appendix

Management and Board Profile

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

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®

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

Dr. Vimal Mehta, CEO

BioXcel Therapeutics, New Haven, CT 06511

vmehta@bioxceltherapeutics.com