UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **February 14, 2024**

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, including 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.

On February 14, 2024, BioXcel Therapeutics, Inc. (the "Company") issued an updated corporate presentation, including its clinical development programs and business strategy. A copy of the presentation is furnished hereto as Exhibit 99.1 and is incorporated herein by reference, and will also be available through the "Investors & Media" page of the Company's website at http://www.bioxceltherapeutics.com.

The information in this Current Report on Form 8-K, including Exhibit 99.1 hereto, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	**Description**
99.1	BioXcel Therapeutics, Inc. Presentation, dated February 14, 2024
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

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

Date: February 14, 2024

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

bioxcel therapeutics®

AI-Driven Transformative Medicines in Neuroscience

February 2024

BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | bioxceltherapeutics.com

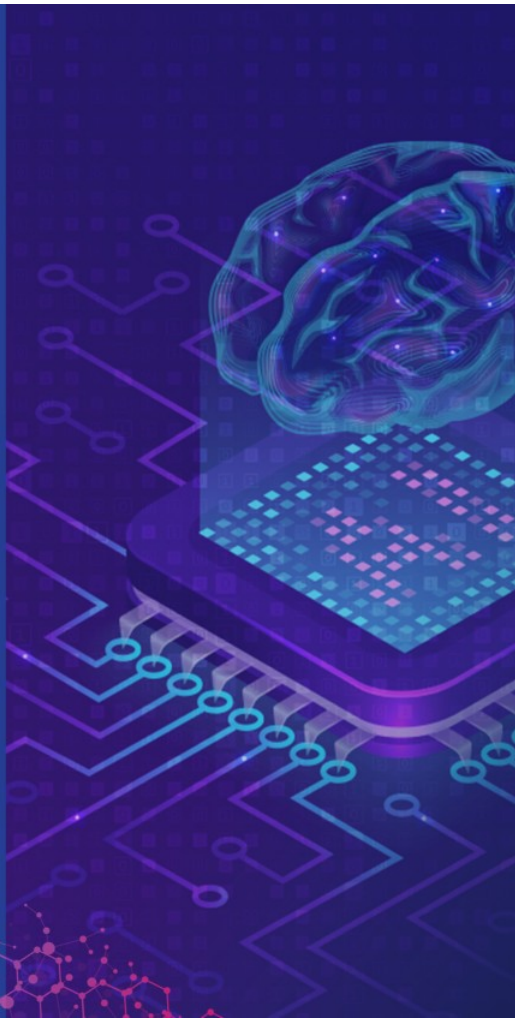
Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking this presentation include but are not limited to: statements regarding BioXcel Therapeutics' expected timing of, and data results from, trials and clin and other milestones involving its product candidates including BXCL501, BXCL502, BXCL503, BXCL504, BXCL701 and BXCL702; paths to poter approvals for BXCL501; the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory appr product candidates; its commercial plan, targets, and strategy for IGALMI™; strategic options for OnkosXcel; potential benefits of treatment with BX BXCL701, potential market size and opportunity for products and product candidates; and its future financial and operational results. When used h including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. In additi statements or information that refer to expectations, beliefs, plans, projections, objectives, performance, or other characterizations of future events circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon BioXcel Therapeutics' cu expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inhe uncertain.

BioXcel Therapeutics may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those descril by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug develop related to the TRANQUILITY II Phase 3 trial; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502, BXCL701 a and other product candidates; the Company has no experience in marketing and selling drug products; IGALMI™ or the Company's product candid be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its abi patients in its clinical trials; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and develop product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable from the COVID-19 pandemic; risks associated with the increased scrutiny related to environmental, social and governance (ESG) matters, its abil commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 1 quarterly period ended September 30, 2023, as such factors may be further updated from time to time in its other filings with the SEC, which are a the SEC's website at www.sec.gov and the Investors section of our 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 thi Any such forward-looking statements represent management's estimates as of the date of this presentation. While BioXcel Therapeutics may elect 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 eve views to change. These forward-looking statements should not be relied upon as representing BioXcel Therapeutics' views as of any date subsequ of this presentation.

Corporate Overview



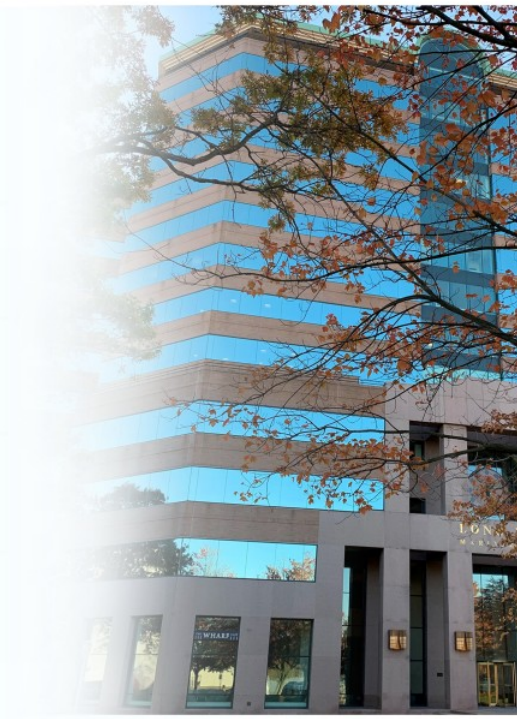
About BioXcel Therapeutics

Founded: 2017

IPO: 2018

Ticker: BTAI (Nasdaq)

Headquarters: New Haven, CT




Our Miss
Develop transformat
medicines in neuros
utilizing artificial inte

Strong Value Proposition and Long-Term Growth Potential

Transformative approach leveraging technology, clinical, and commercial expertise

Unique Business Model

- Employ AI, machine learning, and neuroscience expertise to discover new lead co
- Re-innovate approved and/or clinically developed compounds with established sa
- Optimize R&D for potentially quicker and more successful drug development

Clinically & Commercially Validated AI Platform

- Proven model: BXCL501 IND to IGALMI™ approval < 4 years
- IGALMI approved for acute treatment of agitation associated with schizophrenia o disorder in adults under healthcare provider supervision[1]

Phase 3 Programs

- TRANQUILITY: potential at-home acute treatment of agitation associated with Alz (AAD)
- SERENITY: potential at-home acute treatment of agitation associated with bipolar schizophrenia

Large U.S. At-Home Market Opportunity

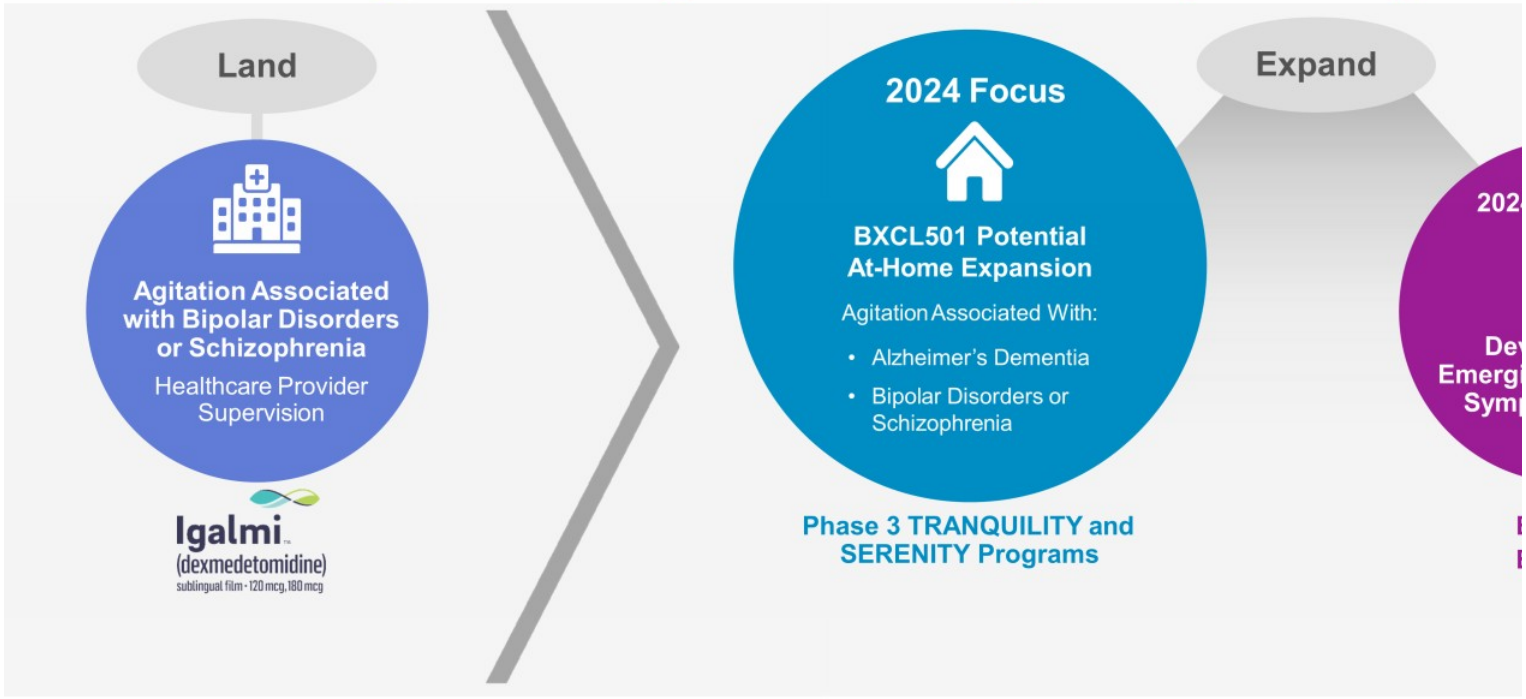
- ~$14+ billion potential market opportunity in AAD[2]
- ~$4+ billion potential market opportunity in bipolar disorders/schizophrenia agitati

1. IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics Inc.; 2022.
2. Based on internal company estimates, prevalence literature, and market research

Market opportunities are based on and subject to labeling, IP restrictions, and generic competition

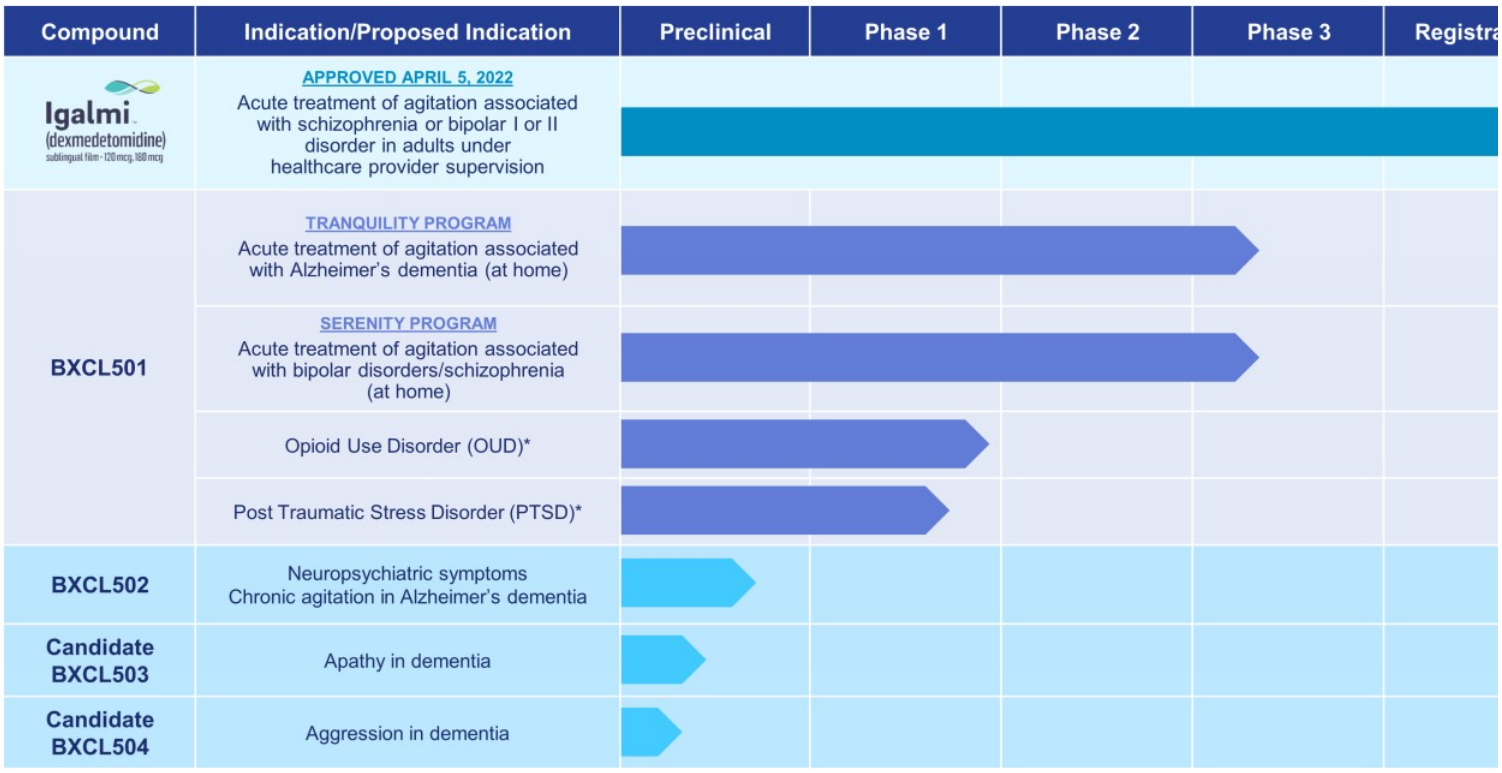
Corporate Growth Drivers

Transformative drug re-innovation approach resulted in rapid development and approval



The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

R&D Strategy: Build Pipeline Depth with Innovation and Ex



*Government-funded, investigator-sponsored trials

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established

Pipeline as of February 14, 2024

Leadership Expertise

Vimal Mehta, Ph.D.
Chief Executive Officer & Founder

BioXcel
inpharmatica
JUBILANT LIFESCIENCES
CuraGen Corporation

Richard I. Steinhart
Senior Vice President & Chief Financial Officer

MELA Sciences
remedy
pwc

Frank D. Yocca, Ph.D.
Senior Vice President & Chief Scientific Officer

Bristol Myers Squibb
AstraZeneca
BioXcel

Vincent J. O'Neill, M.D.
Executive Vice President, Chief of Product Development and Medical Officer

sanofi
Genentech
A Member of the Roche Group
gsk

Matt Wiley
Senior Vice President & Chief Commercial Officer

VYNE THERAPEUTICS
Jazz Pharmaceuticals
AZUR PHARMA

Robert Risinger, M.D.
Chief Medical Officer, Neuroscience

Ortho Mcneil Janssen Pharmaceuticals
Bristol Myers Squibb
Alkermes

Chetan D. Lath Ph.D.
Senior Vice Preside
Head of Regulatory

ALEXIO
BAYER
WARNER LAMBER

Acute Treatment of Agitation Associated with Alzheimer's Dementia (AAD)

TRANQUILITY Program

Potential Sizeable At-Home U.S. Market Opportunity

Agitation associated with Alzheimer's dementia (AAD)

~1.9M[1-4]

Diagnosed Patients with Agitation

Avera
~6 epis
per mo

140M annual episodes*

~$14B+ total market opportunity[6]

1. Alzheimer's Association. 2023 Alzheimer's Disease Facts and Figures. Accessed November 14, 2023. https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf.
2. Data on File. BioXcel Therapeutics, Inc. New Haven, CT.
3. Halpern R, Seare J, et al. Using electronic health records to estimate the prevalence of agitation in Alzheimer disease/dementia.. Int J Geriatri Psychiatry. 2019; 34: 420-431.
4. Lepoore, M, Ferrell A, & Wiener, J. (2017). Living Arrangements of People with Alzheimer's disease and related dementias: Implications for services and supports. Accessed November 14, 2023. https://aspe.hhs.gov/sites/default/files/private/pdf/257966/LivingArran.pdf.
5 Company sponsored market research inVibe-Outpatient Agitation Exploration (ALZ)_v5 (08.29.23)
6 Based on internal company estimates, prevalence literature, and market research

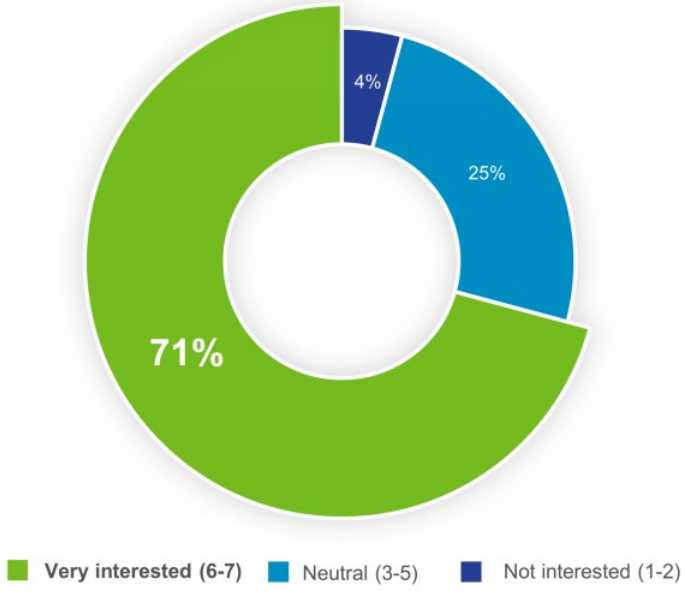
Market opportunities are based on and subject to labeling, IP restrictions, and generic competition
*1.9 million X 6.1 episodes per month X 12 (to annualize)=139 million (or 100+) episodes per year

Favorable Impressions of Target Profile for BXCL501 in AA

Caregivers very interested in blinded target product profile

Interest in Target Profile for BXCL501

(% of Total CGs, n=75)



> "I think a **quick-acting medicine** like that would be **very helpful** all the way around just because **it can get into the system quickly** and stop and possibly help with the episode."
>
> *– Alzheimer's Dementia Caregiver, Sept 2022*

Source: inVibe Market Research with AAD Caregivers (n=75), September 2022

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

TRANQUILITY Program Overview*

Agitation associated with Alzheimer's dementia (AAD)

TRANQUILITY I	TRANQUILITY II	TRANQUILITY AT-HOME *(planned)* 4 weeks
Phase 1b/2	Phase 3	Phase 3
Efficacy, safety, tolerability, and pharmacokinetics of BXCL501 (various doses) vs. placebo (dose-finding trial)	Efficacy, safety, and tolerability of BXCL501 40 mcg or 60 mcg vs. placebo in patients with mild to moderate Alzheimer's disease	Safety and feasibility of BXCL501 60 r placebo in patients with mild, modera severe Alzheimer's disease
Randomized, double-blind, placebo-controlled trial in residential care facilities	Randomized, double-blind, placebo-controlled trial in residential care facilities	Randomized, double-blind, placebo-controlled tri in at-home setting
Completed	Completed	Protocol under review

*An Instructions For Use (IFU) study is being conducted as a brief precursor to at-home trial.

TRANQUILITY Program Overview*

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Completed	Completed	Protocol under review

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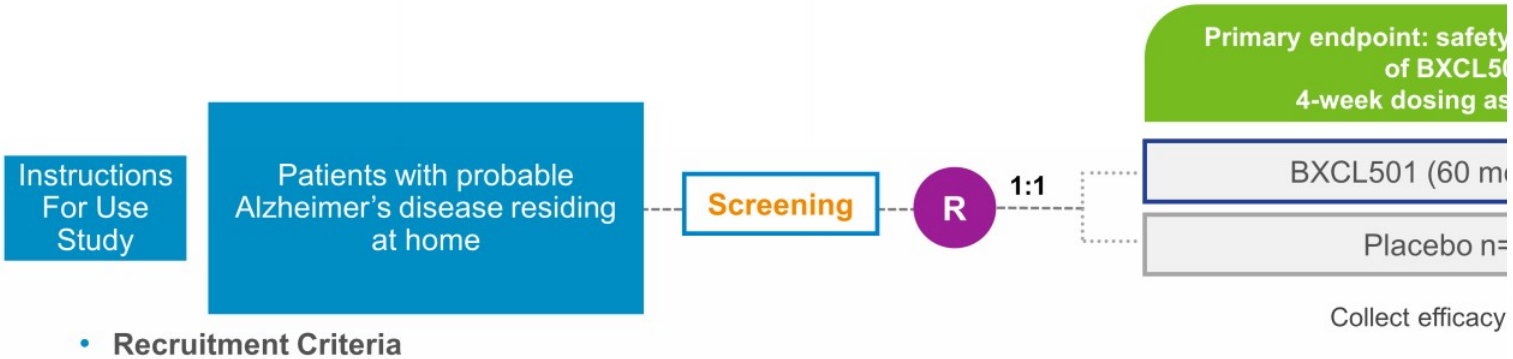
Planned TRANQUILITY At-Home Pivotal Phase 3 Trial Desi

FDA Breakthrough Therapy Type B meeting scheduled for February 20, 2024



- **Recruitment Criteria**
  - Patients with mild, moderate, and severe dementia and full spectrum of agitation
  - Patients with caregivers with not more than three episodes of agitation per week
- **Treatment**
  - Single dose to treat agitation at levels that typically require intervention
  - Maximum of 1 dose of study medication within 12 hours

Expected Topline Data Readout in Q1 2025

*Subject to alignment with FDA on trial design

BXCL501 Clinical Foundation: Expansion Into At-Home Se

- 11 double-blind, placebo-controlled Phase 2 and 3 clinical trials evaluating safety and efficacy
- 1,100+ patients enrolled across multiple neuropsychiatric conditions and in healthy volunteers
- 273 were over 60 years of age and 204 were over 65 years of age who have received doses of
- No unexpected safety signals
  - No reports of serious adverse events or falls related to study drug
  - No drug-related deaths

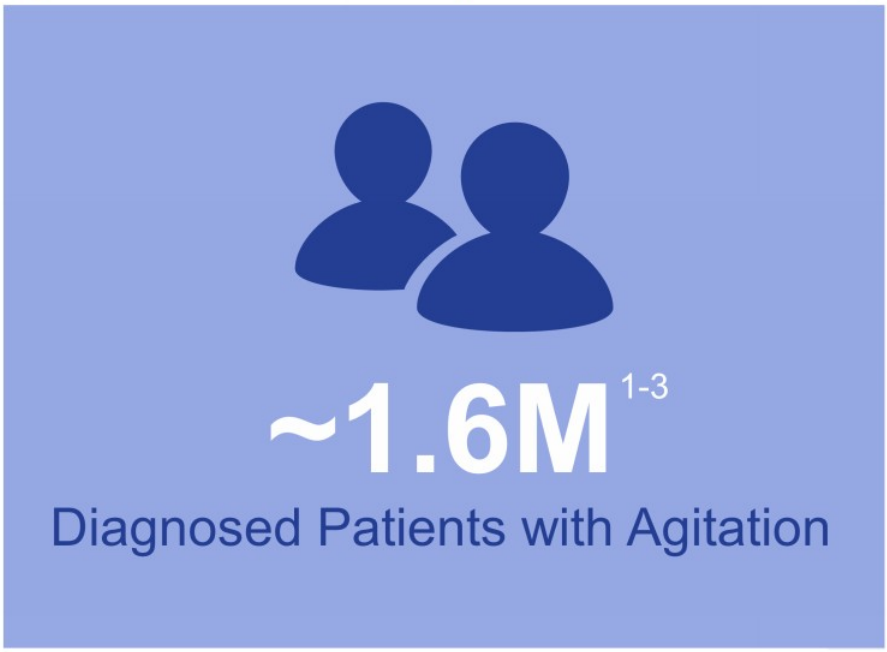
Vast amounts of data from thousands of patients in clinical and real-world s

Acute Treatment of Agitation Associated with Bipolar Disorders or Schizophrenia *(at-home setting)*

SERENITY Program

Potential Sizeable At-Home U.S. Market Opportunity

Agitation associated with bipolar disorders or schizophrenia



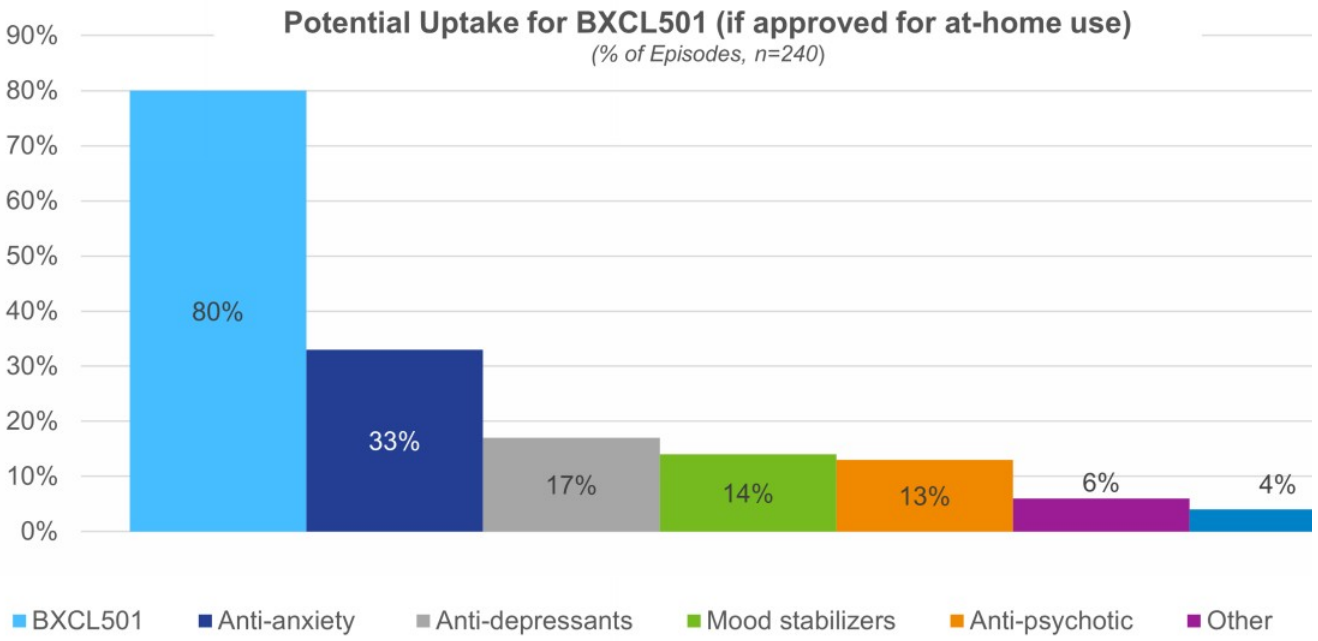
40M+ annual episodes outside hospital setting*

~$4B+ total market opportunity[5]

1 Wu E. Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. Psychological Medicine, 2006,
2 NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf
3 Symphony APLD Data
4 Company Sponsored Market Research (inVibe-BPD-SCZ Agitation Landscape (04.24.23)v5)
5 Based on internal company estimates, prevalence literature, and market research (~$4 billion market opportunity excludes 16 million episodes that occur in the hospital setting)
Market opportunities are based on and subject to labeling, IP restrictions, and generic competition
*1.6 million X 3 episodes per month X12 (to annualize)=58 million episoides-16 million institutional episodes = 42 (or 40+) million annual at home episodes

Potential for Patient Use of BXCL501 At Home

When shown product profile stimulus, patients said they would use the targeted product
their bipolar/schizophrenia agitation episodes, and for those on therapy it would be addi



Q22. You previously indicated that you used the following medications to manage your last 3 agitation episodes. Now please imagine that Igalmi was also available for you to use. Please indicate what treatment you would have chosen to treat the last 3 episodes if Igalmi were also available to you. We have provided your previous below for reference.

Source: InVibe Feb 2023

SERENITY Program Overview*

Acute treatment of agitation associated with bipolar disorders or schizophrenia

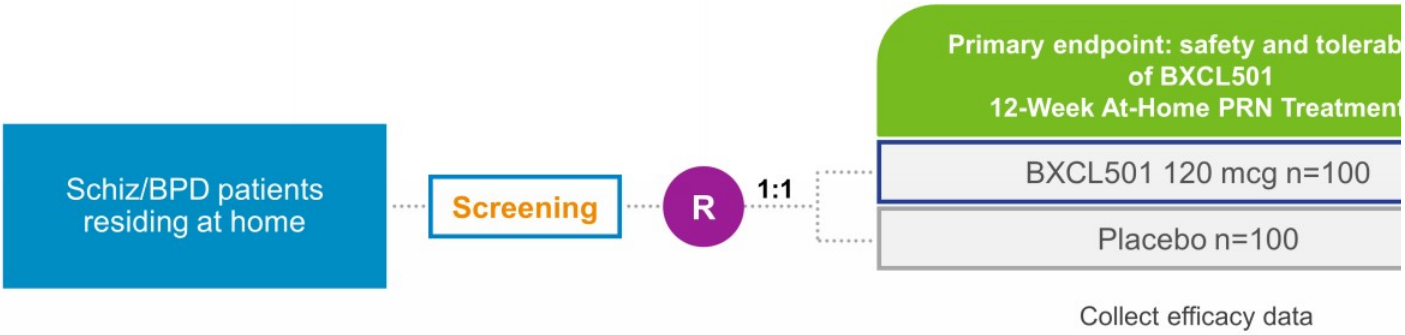
SERENITY I (schizophrenia-associated agitation)	SERENITY II (bipolar disorder-associated agitation)	SERENITY AT-HOME (*planned*) (bipolar disorder or schizophrenia-associated agitation) **(12-WEEKS)**
Phase 3	Phase 3	Phase 3**
Efficacy, safety, and tolerability of BXCL501 120 mcg or 180 mcg vs. placebo	Efficacy, safety, and tolerability of BXCL501 120 mcg or 180 mcg vs. placebo	Safety and tolerability of BXCL501 120 mcg vs. placebo
Randomized, double-blind, placebo-controlled trial in a medically supervised setting	Randomized, double-blind, placebo-controlled trial in a medically supervised setting	Randomized, double-blind, placebo-controlled trial in at-home setting
Completed	Completed	Protocol under review

*Not shown are 2 additional post-marketing requirement studies in schizophrenia & bipolar disorder:
- Agitation in Pediatric Schizophrenia & BP Disorder
- Tachyphylaxis, Tolerance, & Withdrawal

**Completed efficacy, safety, and tolerability study of BXCL501 60 mcg vs. placebo; randomized, double-blind, placebo-controlled trial conducted in a medically supervised setting

Planned SERENITY At-home Pivotal Phase 3 Trial Design*

FDA Type C meeting scheduled for March 6, 2024



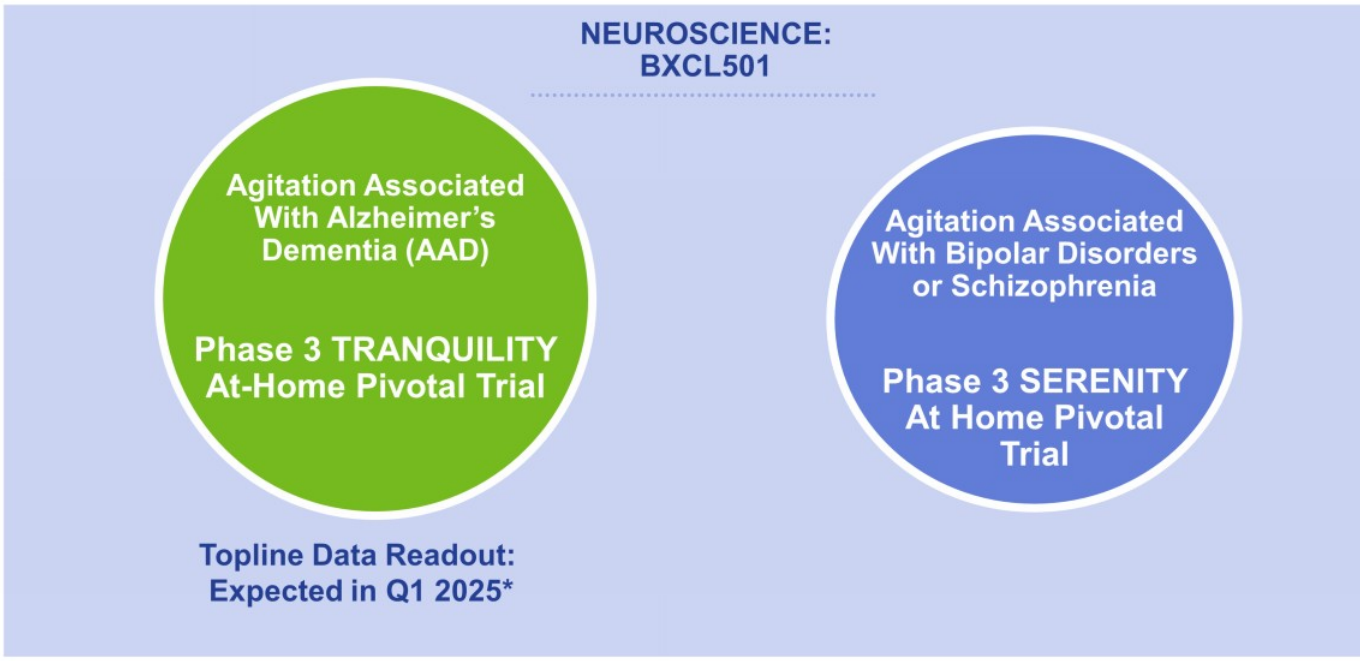
- **Recruitment Criteria**
  - Patients alone or with informants (as dyads) with at least 1 treated episode of agitation
- **Treatment**
  - Single dose to treat agitation at levels that typically require intervention
  - Maximum of 1 dose of study medication within 12 hours

*Subject to alignment with FDA on trial design

Upcoming Expected Milestones

Expected BXCL501 Clinical Trial Initiations in H1 2024

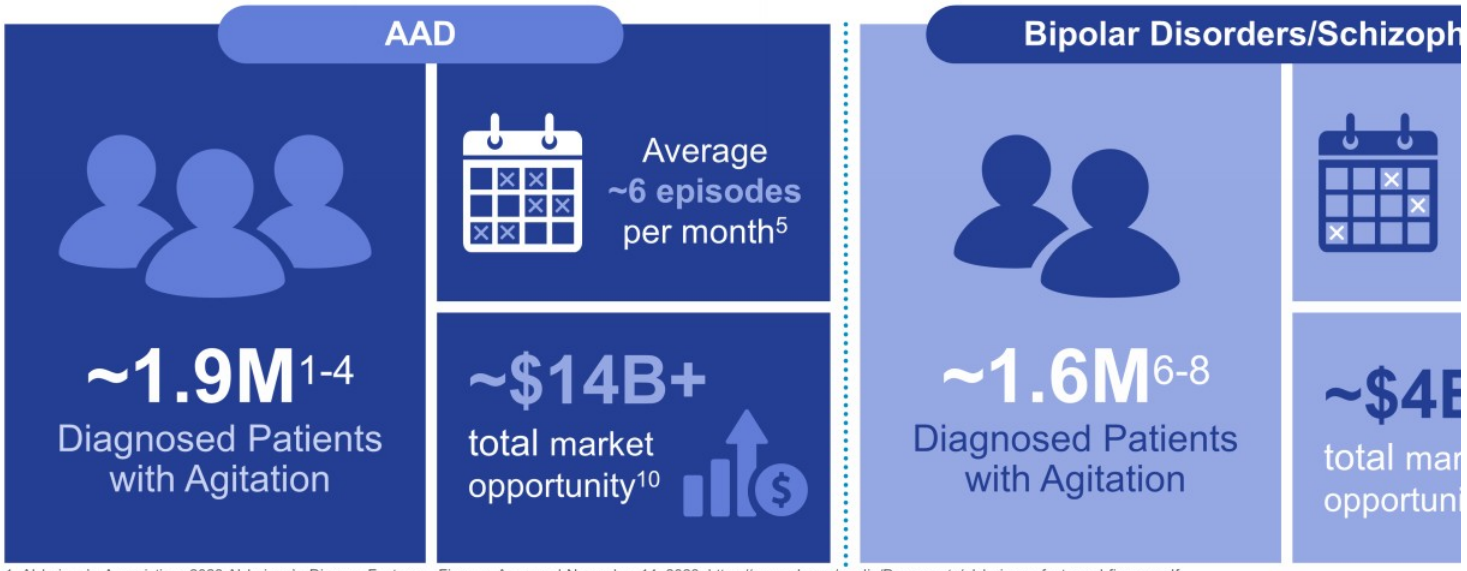
TRANQUILITY At Home: highest priority for capital allocation



*Subject to alignment with FDA on trial design

Potential Sizeable At-Home U.S. Market Opportunities

Agitation associated with Alzheimer's dementia (AAD) and bipolar disorders or schizoph



1. Alzheimer's Association. 2023 Alzheimer's Disease Facts an Figures. Accessed November 14, 2023. https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf.
2. Data on File. BioXcel Therapeutics, Inc. New Haven, CT.
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4. Lepoore, M, Ferrell A, & Wiener, J. (2017). Living Arrangements of People with Alzheimer's disease and related dementias: Implications for services and supports. Accessed November 14, 2023. https://aspe.hhs.gov/sites/default/files/private/pdf/257966/LivingArran.pdf.
5 inVibe-Outpatient Agitation Exploration (ALZ)_v5 (08.29.23)
6 Wu E. Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. Psychological Medicine, 2006,
7 NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf
8 Symphony APLD Data
9 InVibe-BPD-SCZ Agitation Landscape (04.24.23)v5
10 Based on internal company estimates, prevalence literature, and market research

Market opportunities are based on and subject to labeling, IP restrictions, and generic competition

IGALMI™ Commercialization

Following commercial field workforce reduction in August 2023

IGALMI™ (dexmedetomidine) Sublingual Film

First and only orally dissolving sublingual film currently in use under healthcare provider for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder i

Noninvasive, self-administered film[1-4] covering mild, moderate, and severe agitation

- Rapid absorption of dexmedetomidine into the bloodstrea mucosa[1]
- Mucoadhesive film, designed so it cannot be spit out or s
- Sublingual or buccal placement[1]
- Mint-flavored[1]

IGALMI was not studied for longer than 24 hours after the first dose. There may be a risk of physical dependence, a withdrawal syndrome, tolerance, and/or tachyphylaxis if IGALMI is used in a manner other than indicated.

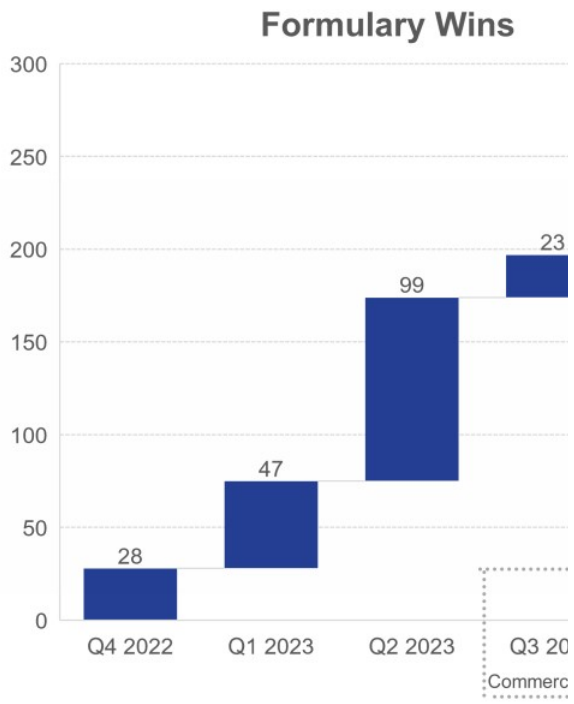
1. IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics Inc.; 2022.
2. Data on file. BXCL501-301 CSR (SERENITY I). BioXcel Therapeutics, Inc.; January 2021
3. Data on file. BXCL501-302 CSR (SERENITY II). BioXcel Therapeutics, Inc.; January 2021.
4. Preskorn SH, et al. Effect of Sublingual Dexmedetomidine vs Placebo on Acute Agitation Associated With Bipolar Disorder A Randomized Clinical Trial. *JAMA*. 2022;327(8):727-736.

Please see Important Safety Information at the end of this presentation.

Creating Demand in 2024

J-Code issuance, P&T formulary wins, and volume contracting to drive commercial prog following commercial field workforce reduction

- Targeting/engaged with key hospital systems for volume-based contracting
- J-Code granted by CMS effective Jan. 1, 2024 *(streamlines and standardizes reimbursement)*
- Over 250 hospital P&T approvals to date, with large volume in Q4 2023
- First large academic center approval in Q4 2023
- Activating new channels such as Dept. of Veterans Affairs and Dept. of Corrections



Source: Data on File, 2023

Agitation Franchise Expansion Plan

Seek approvals for BXCL501 for agitation associated with bipolar disorder, schizophrenia, and Alzheimer's dementia in all settings

2022-2023

Launch & establish IGALMI™ in hospital setting for bipolar disorder/ schizophrenia

Use contracting and pricing to drive familiarity with IGALMI in hospitals

Igalmi™
(dexmedetomidine)
sublingual film - 120 mcg, 180 mcg

2024

Prepare for potential expansion into at-home markets for BXCL501

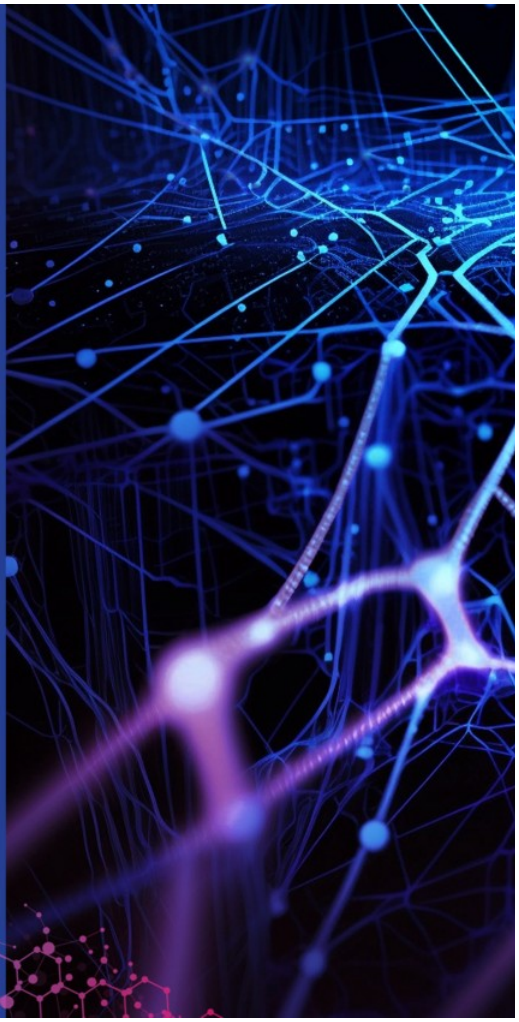
Leverage patient and HCP experiences to prepare for at-home launches if approved

2025

Potential launch for approved indications for BXCL501 in at-home settings

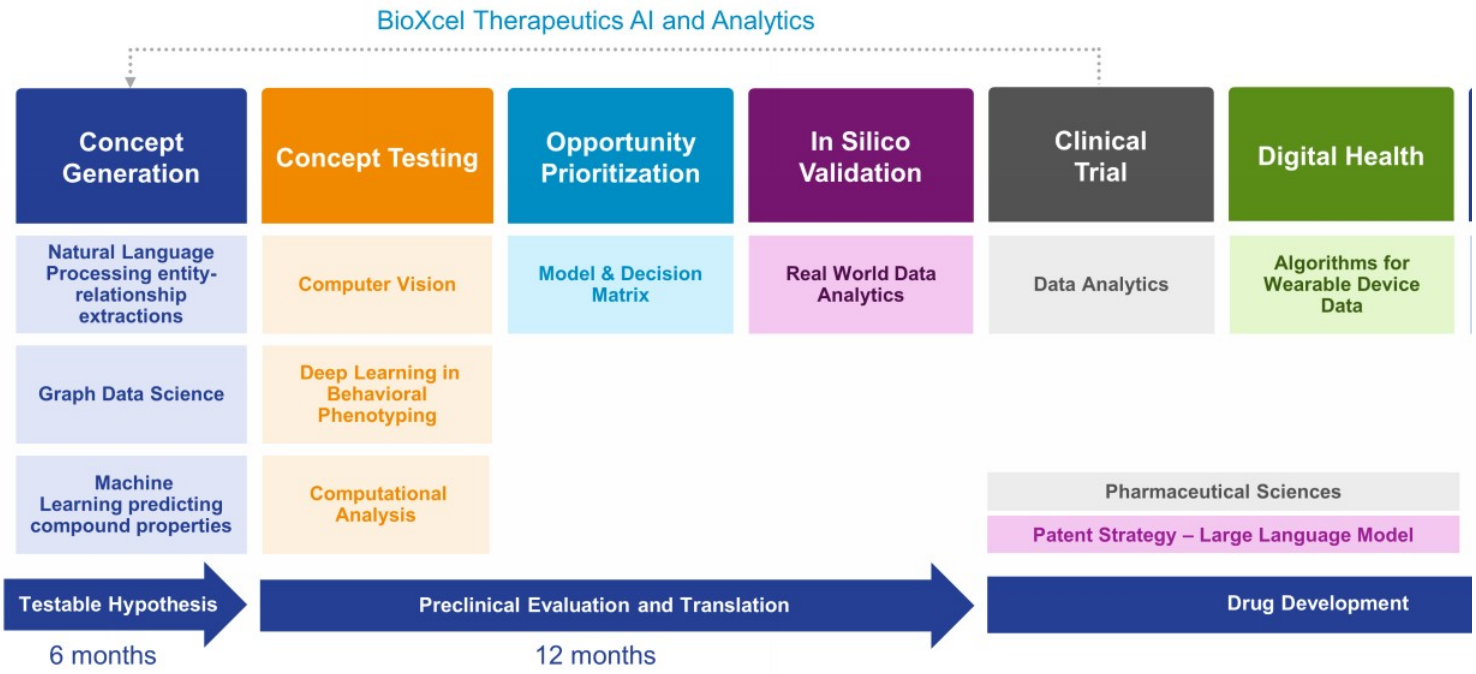
If approved, launch with established payor contracts, experienced (hospital) advocates, and DTC/PR campaign

AI-Driven Drug Re-innovation Platform

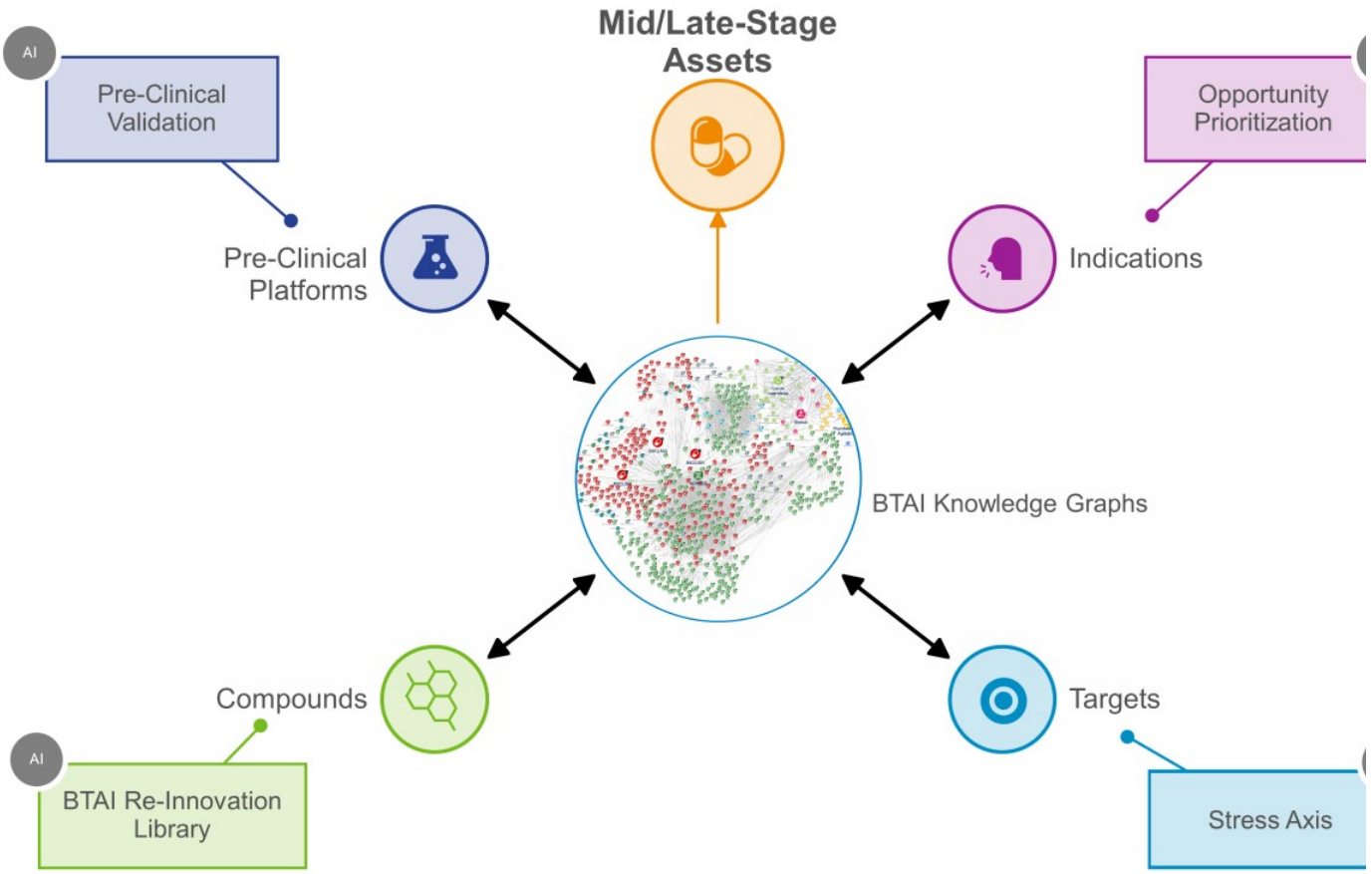


AI Strategy to Accelerate Drug Re-Innovation Process

From product concept to first-in-human clinical trials using composite AI

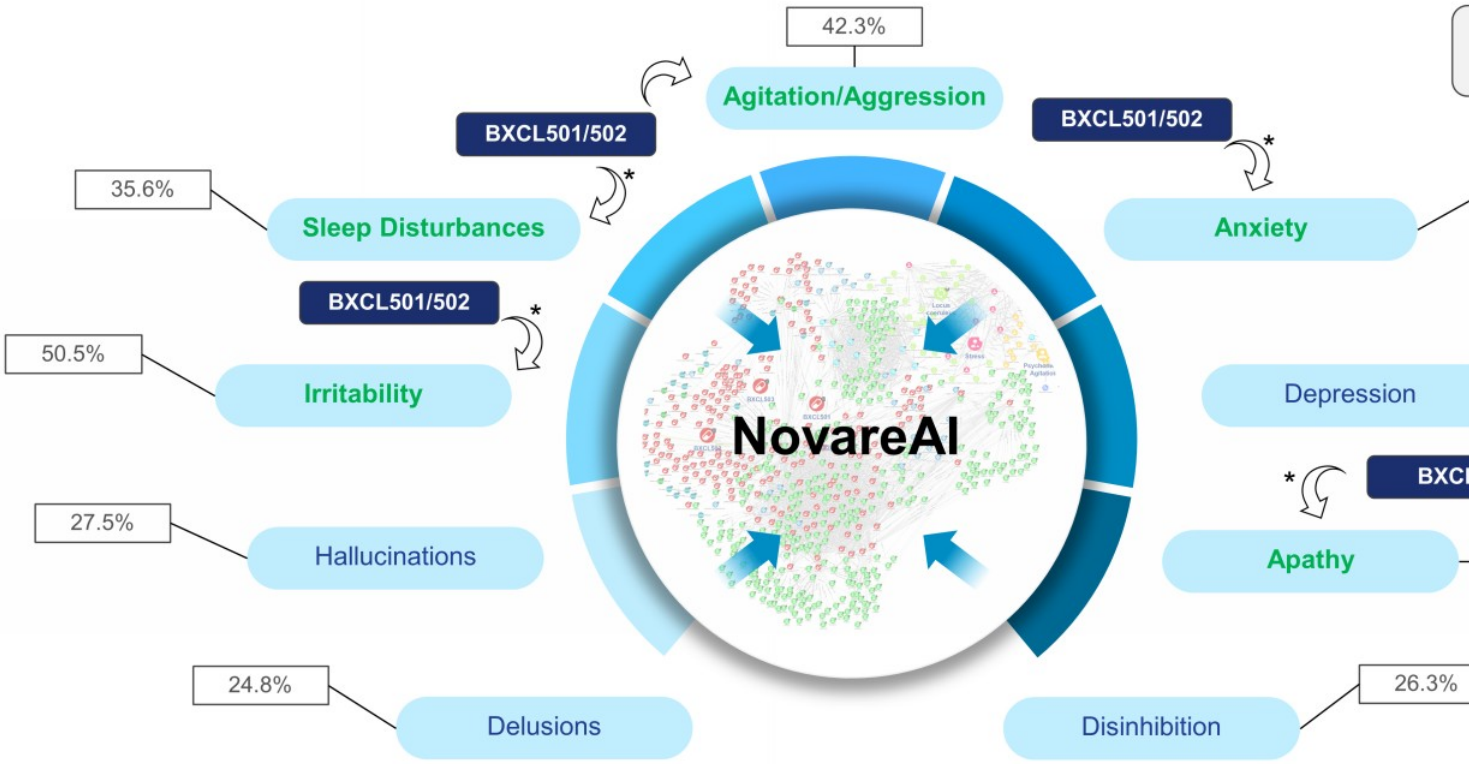


NovareAI: Ecosystem for Drug Discovery and Developmen



Behavioral and Psychological Symptoms in Alzheimer's D

Identifying targets and compounds designed to address unmet medical needs in demen



* Denotes a potential role for BXCL502 and BXCL503 in addressing these symptoms
The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.
Prevalences derived from Laganà et al., Neuropsychiatric or Behavioral and Psychological Symptoms of Dementia (BPSD): Focus on Prevalence and Natural History in Alzheimer's Disease and Frontotemporal Dementia; Front Neurol 2022;13 832199

BXCL502:
A Novel Agent for Treatment of Chronic Agitation in Dementia

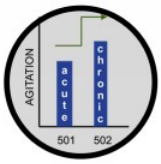
BXCL502 Presents a Compelling Value Proposition

Formulation studies are ongoing

New Chemical Entity → **BXCL502 is a novel formulation of latrepirdine an metabolic stabilizer**

Improved Understanding of Proposed Mechanism → **Potentially blocks excessive signaling mediated neurotransmitters: serotonin and norepinephri (noradrenaline)**

Re-Innovation of Latrepirdine → **Improved PK results suggest potential for once-d dosing, which could be suitable for chronic agita**

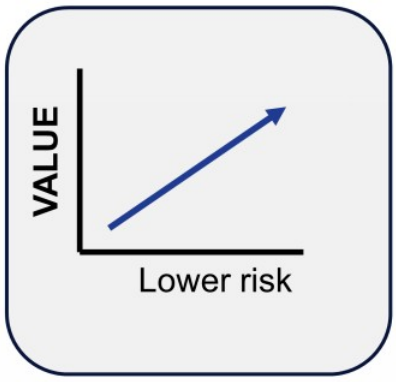


Synergistic with Portfolio → **Expanding agitation development programs fro episodic to chronic**

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

Latrepirdine (Dimebon): Clinical Safety Results, Preclinica Confidence in Rationale, and Early Sign of Potential Effica

Data support development for treatment of neuropsychiatric symptoms associated with



SAFETY RESULTS IN PATIENTS

- Over 1000 patients wit exposed for 26 weeks to 52 weeks

(*Trials conducted by Pfizer and*

PRECLINICAL Confidence in Rationale

- Showed activity in 5 pr models of neuropsychi symptoms

(*Trials conducted by BioXcel Th*

CLINICAL Early Sign of Potential Efficacy

- Secondary efficacy en changes in Neuropsyc Inventory (NPI), showe superiority over placeb

(*Trials conducted by Pfizer and*

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Recent Examples of Successful CNS Drug Re-Innovation

DRUG/COMPANY	CHALLENGE	SOLUTION	STATUS
Dextromethorphan Axsome Therapeutics	Metabolites cause unwanted side effects	Block metabolism with CYP2D6 inhibitor, bupropion	Successful clinic trial/depressio
Xanomeline Karuna Therapeutics	Peripheral side effects	Block peripheral effects with trospium	Successful clinic trial/schizophrer
Dexmedetomidine IGALMI™ BioXcel Therapeutics	Poor oral bioavailability (<20%)	Use sublingual film to administer directly to blood (oral bioavailability >80%)	Approved to tre adults with agitat associated wit schizophrenia bipolar I or II diso

Latrepirdine + "Metabolic Stabilizer" = BXCL502

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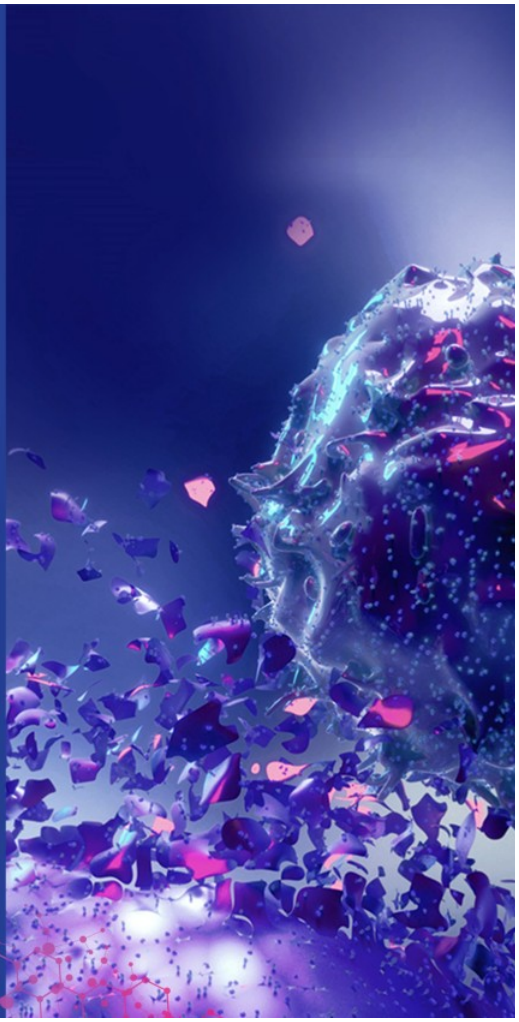
Immuno-Oncology

OnkosXcel Therapeutics™

A subsidiary of BioXcel Therapeutics, Inc.



BXCL701: Strong Value Proposition in Hard-to-Treat Tumo

Novel Mechanism of Action
Data Published in JITC

- One of the most clinically advanced oral innate immune activators[1]
- Designed to activate inflammasome via DPP8/9 inhibition

Clinical Proof of Concep
Cold Tumors

- Positive results in two cold tumor types: neuroendocrine prostate cancer (SCNC adenocarcinoma
- Full Phase 2a data presented at PCF 2
- 800+-subject clinical safety database

Leadership Position in Innate Immunity
DPP8/9 Biology

FortySeven acquired for ~$5B by GILEAD

Trillium acquired for ~$2.3B by Pfizer

Scarcity of assets in innate immunity

Exploring Strategic Optic

- Including potential financing, strategic pa M&A

BXCL701 (talabostat) is an investigational agent. The safety and efficacy have not been established.

1. National Library of Medicine. Accessed January 4, 2024, clinicaltrials.gov.

Immuno-Oncology Clinical Development

Compound	Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Expected Upcoming Milestone
BXCL701 Company-sponsored trials	Small Cell Neuroendocrine Prostate Cancer (SCNC)					FDA Meeting
	Small Cell Lung Cancer (SCLC)					Initiate Phase 1b/2
BXCL701 Investigator-sponsored trials	Metastatic Pancreatic Ductal Adenocarcinoma					Phase 2 readout
	Acute Myeloid Leukemia (AML)					Phase 1b readout
BXCL702 BXCL701 follow-on/ novel DPP inhibitor	Solid Tumors					Candidate nomination

As of February 14, 2024

The safety and efficacy of these investigational agents have not been established.

Thank you!

BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | bioxceltherapeutics.com

Appendix

IGALMI™ Indication and Important Safety Information

INDICATION
IGALMI™ (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, that is placed under the tongue and is used for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not be hours from the first dose. It is not known if IGALMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION
IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volun high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell provider if they feel dizzy, lightheaded, or faint.
- **Heart rhythm changes (QT interval prolongation).** IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slo potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of to sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.
- **Sleepiness/drowsiness.** Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours
- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, c pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeedi medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they ta lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full Prescribing Information.