



# AI-Driven Transformative Medicines in Neuroscience

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February 2024

# 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 regarding BioXcel Therapeutics' expected timing of, and data results from, trials and clinical studies, and other milestones involving its product candidates including BXCL501, BXCL502, BXCL503, BXCL504, BXCL701 and BXCL702; paths to potential FDA approvals for BXCL501; the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates; its commercial plan, targets, and strategy for IGALMI™; strategic options for OnkosXcel; potential benefits of treatment with BXCL501 and BXCL701, potential market size and opportunity for products and product candidates; and its future financial and operational results. 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 BioXcel Therapeutics' current expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel Therapeutics 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; risks related to the TRANQUILITY II Phase 3 trial; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502, BXCL701 and BXCL702, and other product candidates; the Company has no experience in marketing and selling drug products; IGALMI™ or the Company's product candidates may not be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; risks associated with the increased scrutiny related to environmental, social and governance (ESG) matters, its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the 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 accessible on the SEC's website at [www.sec.gov](http://www.sec.gov) and the Investors section of our website at [www.bioxceltherapeutics.com](http://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 BioXcel Therapeutics 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 BioXcel Therapeutics' views as of any date subsequent to the date of this presentation.

# Corporate Overview





# About BioXcel Therapeutics



**Founded:** 2017



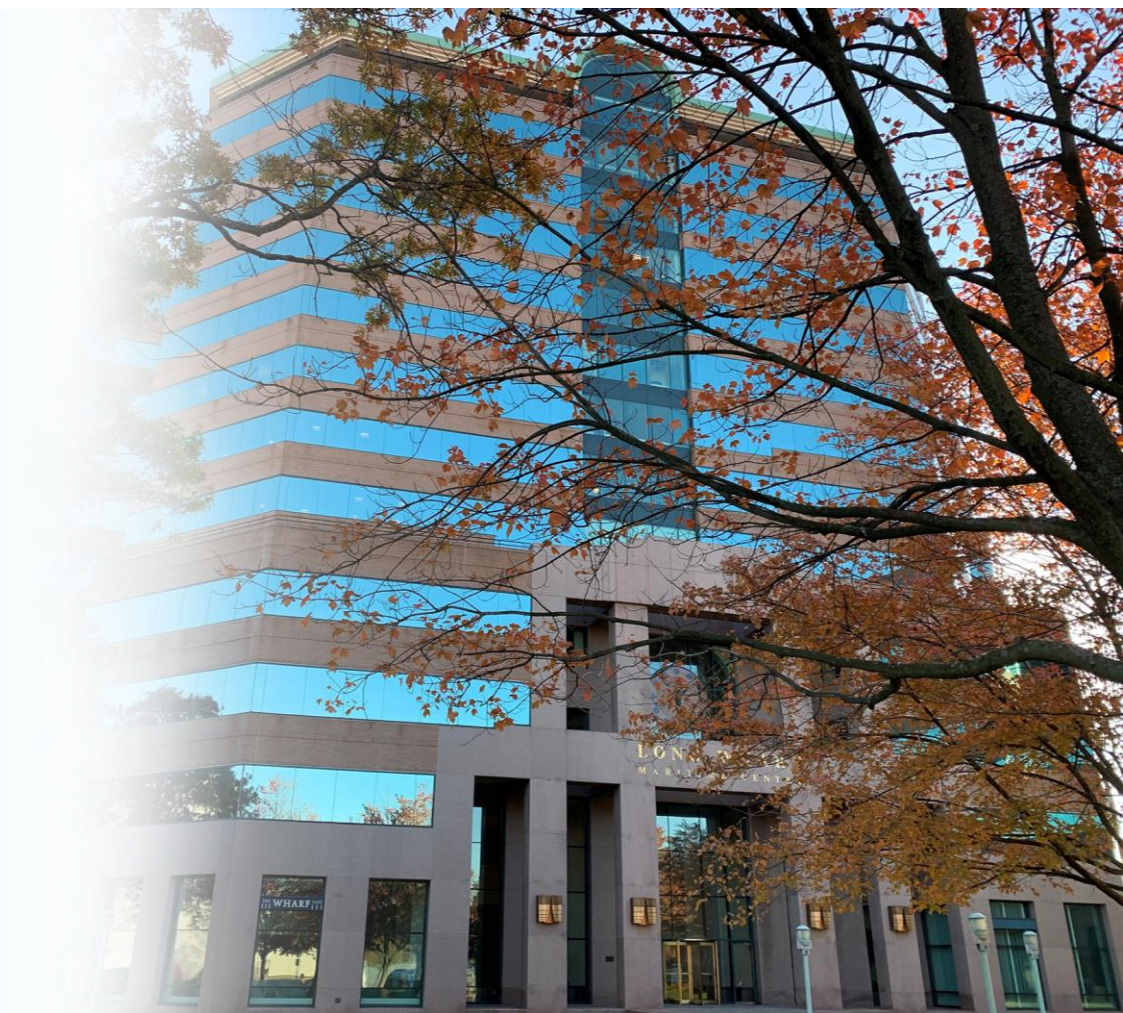
**IPO:** 2018



**Ticker:** BTAI (Nasdaq)



**Headquarters:** New Haven, CT







# Our Mission

Develop transformative  
medicines in neuroscience  
utilizing artificial intelligence

# 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 compounds
- Re-innovate approved and/or clinically developed compounds with established safety data
- 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 or bipolar I or II disorder in adults under healthcare provider supervision<sup>1</sup>



## Phase 3 Programs

- TRANQUILITY: potential at-home acute treatment of agitation associated with Alzheimer's dementia (AAD)
- SERENITY: potential at-home acute treatment of agitation associated with bipolar disorders or schizophrenia



## Large U.S. At-Home Market Opportunity

- ~\$14+ billion potential market opportunity in AAD<sup>2</sup>
- ~\$4+ billion potential market opportunity in bipolar disorders/schizophrenia agitation<sup>2</sup>

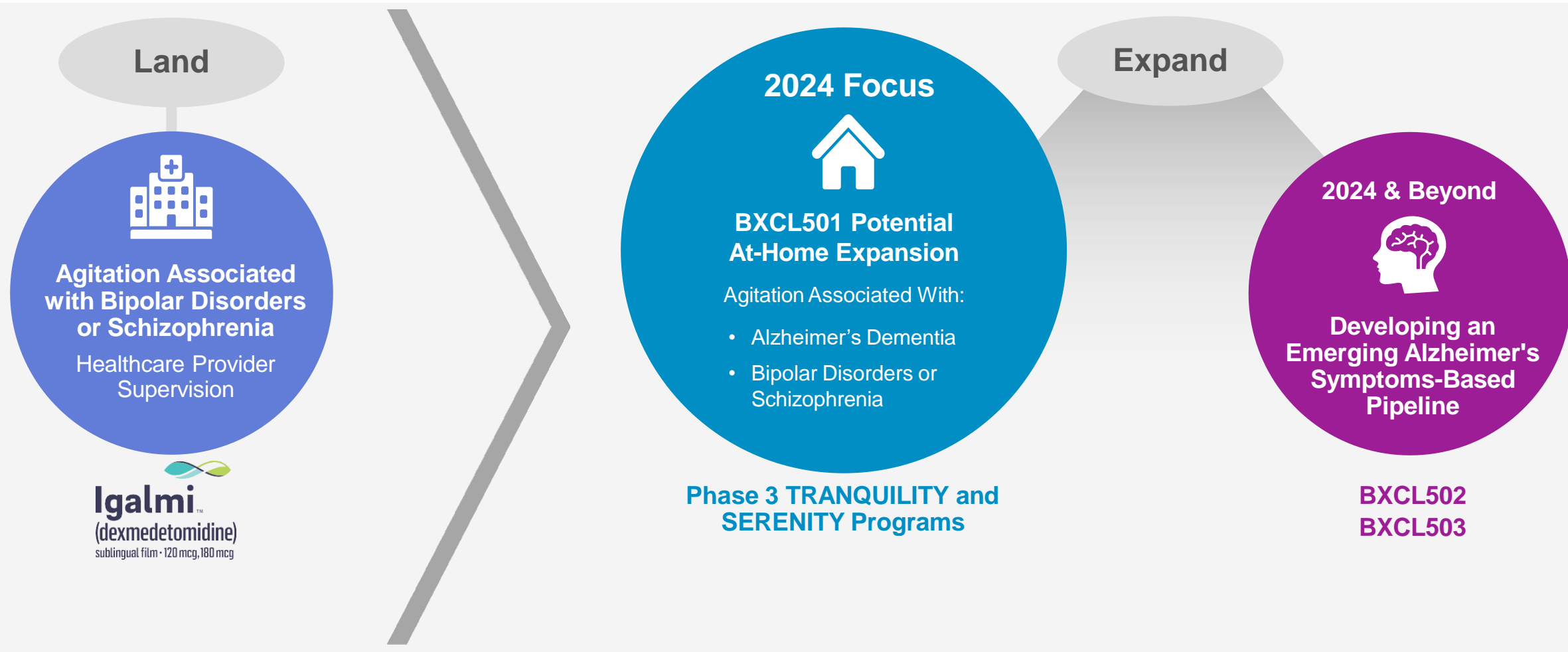
1. IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics Inc.; 2022.

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 of IGALMI™



# R&D Strategy: Build Pipeline Depth with Innovation and Expansion

Compound	Indication/Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Marketed
 <b>Igalmi™</b> (dexmedetomidine) <small>sublingual film - 120 mcg, 180 mcg</small>	<a href="#">APPROVED APRIL 5, 2022</a> Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults under healthcare provider supervision						
<b>BXCL501</b>	<a href="#">TRANQUILITY PROGRAM</a> Acute treatment of agitation associated with Alzheimer's dementia (at home)						
	<a href="#">SERENITY PROGRAM</a> Acute treatment of agitation associated with bipolar disorders/schizophrenia (at home)						
	Opioid Use Disorder (OUD)*						
	Post Traumatic Stress Disorder (PTSD)*						
<b>BXCL502</b>	Neuropsychiatric symptoms Chronic agitation in Alzheimer's dementia						
<b>Candidate BXCL503</b>	Apathy in dementia						
<b>Candidate BXCL504</b>	Aggression in dementia						

\*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



**Richard I. Steinhart**

Senior Vice President &  
Chief Financial Officer



**Frank D. Yocca,  
Ph.D.**

Senior Vice President &  
Chief Scientific Officer



**Vincent J. O'Neill,  
M.D.**

Executive Vice President,  
Chief of Product  
Development and Medical  
Officer



**Matt Wiley**

Senior Vice President &  
Chief Commercial Officer



Jazz Pharmaceuticals®



AZUR PHARMA



**Robert Risinger,  
M.D.**

Chief Medical Officer,  
Neuroscience



**Chetan D. Lathia,  
Ph.D.**

Senior Vice President &  
Head of Regulatory Affairs



**Dusan Kostic,  
Ph.D.**

Vice President,  
Head of Medical Affairs



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

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TRANQUILITY Program



# Potential Sizeable At-Home U.S. Market Opportunity

Agitation associated with Alzheimer's dementia (AAD)



**~1.9M<sup>1-4</sup>**

**Diagnosed Patients with Agitation**



**Average  
~6 episodes  
per month<sup>5</sup>**

**140M** annual episodes\*  
**~\$14B+** total  
market opportunity<sup>6</sup>



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 Geriatr Psychiatry. 2019; 34: 420-431.

4. Lepore, 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

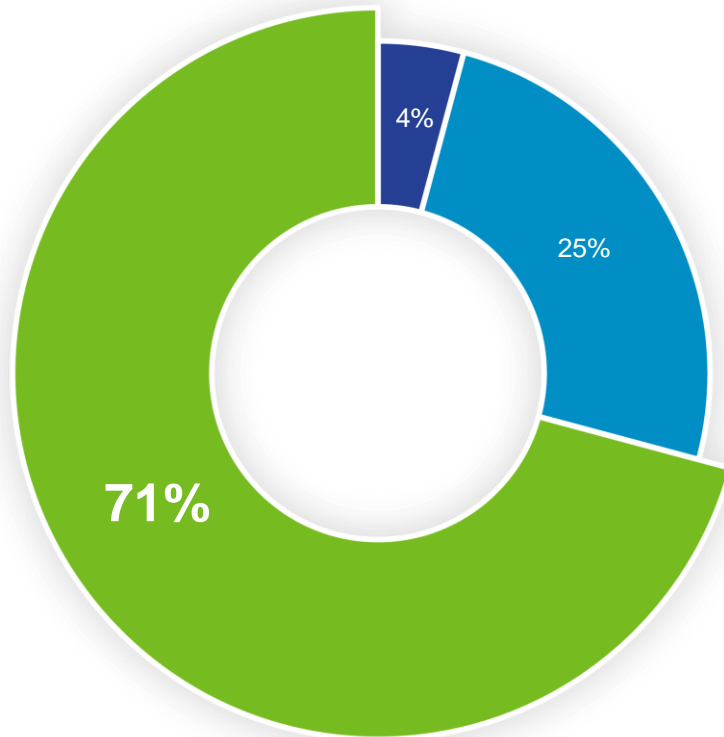
\*1.9 million X 6.1 episodes per month X 12 (to annualize)=139 million (or 100+) episodes per year



# Favorable Impressions of Target Profile for BXCL501 in AAD

Caregivers very interested in blinded target product profile

Interest in Target Profile for BXCL501  
(% of Total CGs, n=75)



■ Very interested (6-7) ■ Neutral (3-5) ■ Not interested (1-2)

“ 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

# TRANQUILITY Program Overview\*

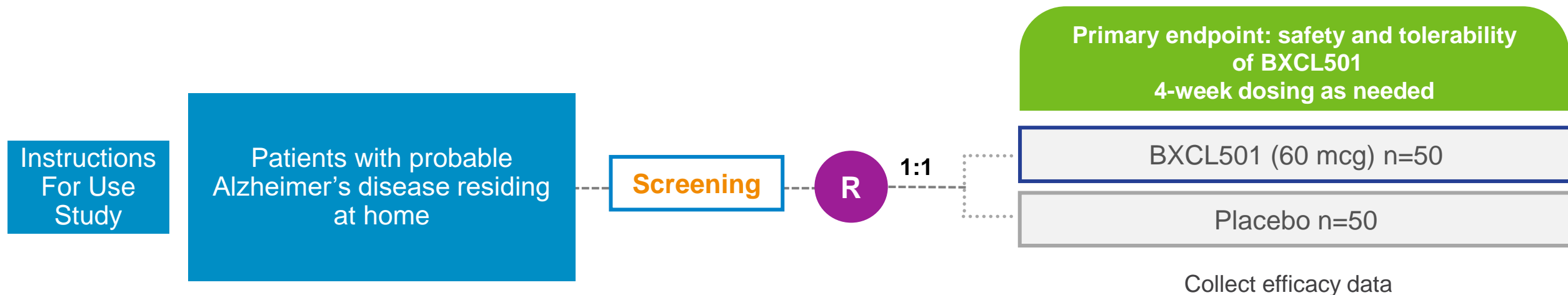
Agitation associated with Alzheimer's dementia (AAD)

TRANQUILITY I	TRANQUILITY II	TRANQUILITY AT-HOME <i>(planned)</i> * 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 mcg vs. placebo in patients with mild, moderate, and 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 trial 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.

# Planned TRANQUILITY At-Home Pivotal Phase 3 Trial Design\*

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 Setting**

- 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 BXCL501
- 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 settings**

# 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



**~1.6M**<sup>1-3</sup>

Diagnosed Patients with Agitation



Average  
**~3 episodes**  
per month<sup>4</sup>

**40M+** annual episodes  
outside hospital setting\*  
**~\$4B+** total market  
opportunity<sup>5</sup>



<sup>1</sup> Wu E. Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. Psychological Medicine, 2006,

<sup>2</sup> 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](https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf)

<sup>3</sup> Symphony APLD Data

<sup>4</sup> Company Sponsored Market Research (inVibe-BPD-SCZ Agitation Landscape (04.24.23)v5)

<sup>5</sup> Based on internal company estimates, prevalence literature, and market research (~\$4 billion market opportunity excludes 16 million episodes that occur in the hospital setting)

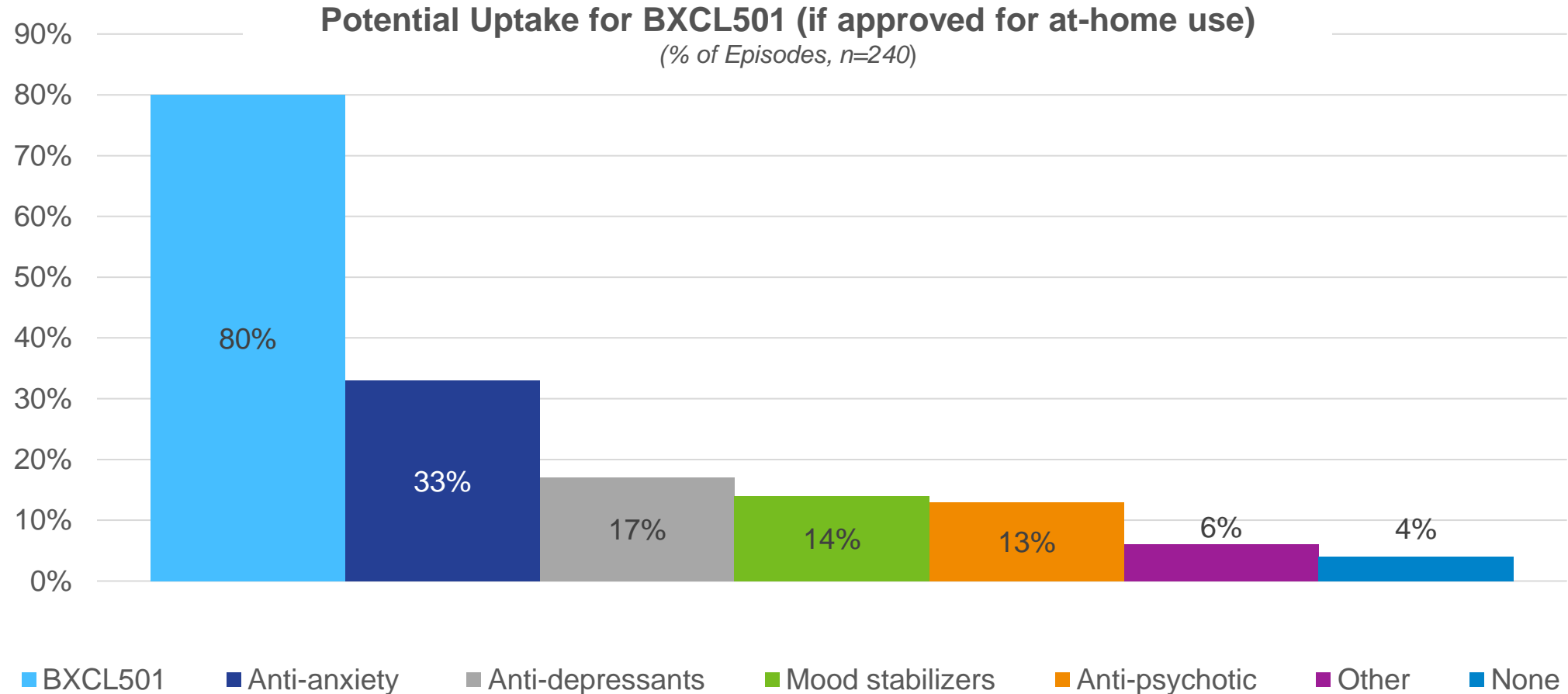
Market opportunities are based on and subject to labeling, IP restrictions, and generic competition

\*1.6 million X 3 episodes per month X12 (to annualize)=58 million episodes-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 for 80% of their bipolar/schizophrenia agitation episodes, and for those on therapy it would be additive.



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.

# 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 ( <i>planned</i> ) (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

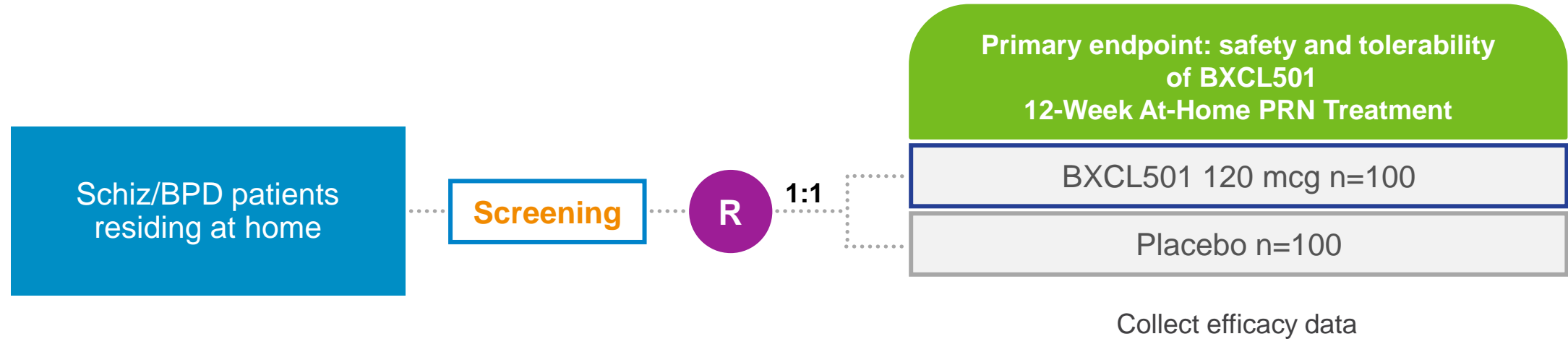
\*Not shown are 2 additional post-marketing requirement studies in schizophrenia & bipolar disorder:

- 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



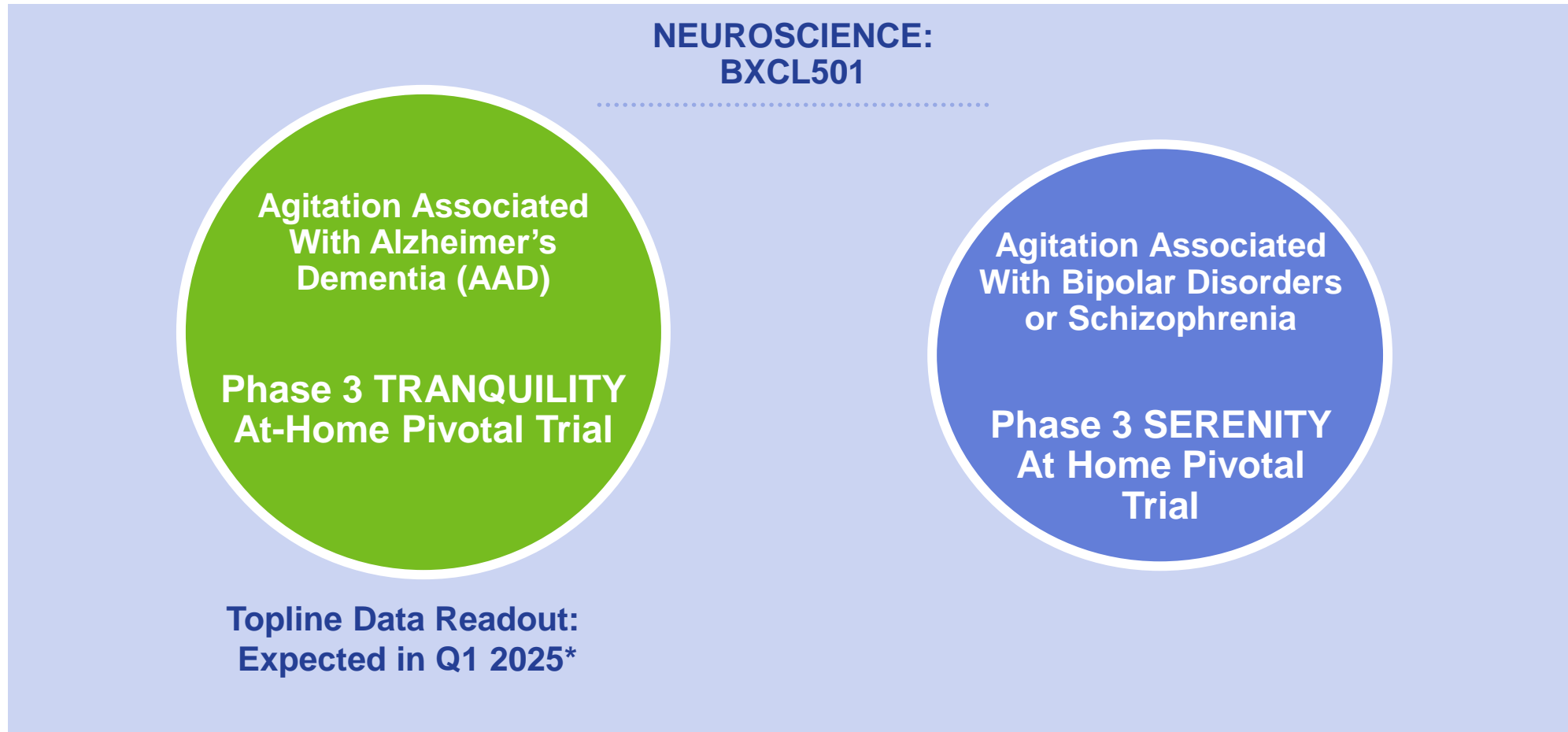
# Upcoming Expected Milestones

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# Expected BXCL501 Clinical Trial Initiations in H1 2024

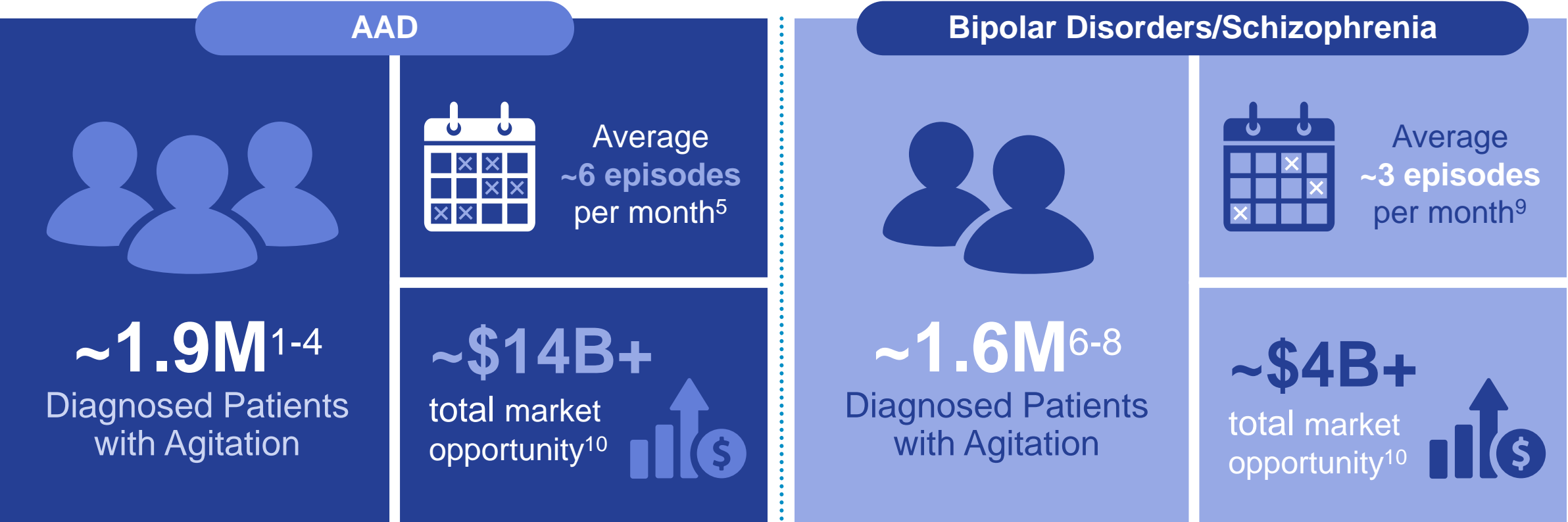
TRANQUILITY At Home: highest priority for capital allocation



\*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 schizophrenia



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 Geriatr 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. 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](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 supervision for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults<sup>1</sup>



Noninvasive, self-administered film<sup>1-4</sup> covering mild, moderate, and severe agitation

- Rapid absorption of dexmedetomidine into the bloodstream via oral mucosa<sup>1</sup>
- Mucoadhesive film, designed so it cannot be spit out or swallowed<sup>1-3</sup>
- Sublingual or buccal placement<sup>1</sup>
- Mint-flavored<sup>1</sup>

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.

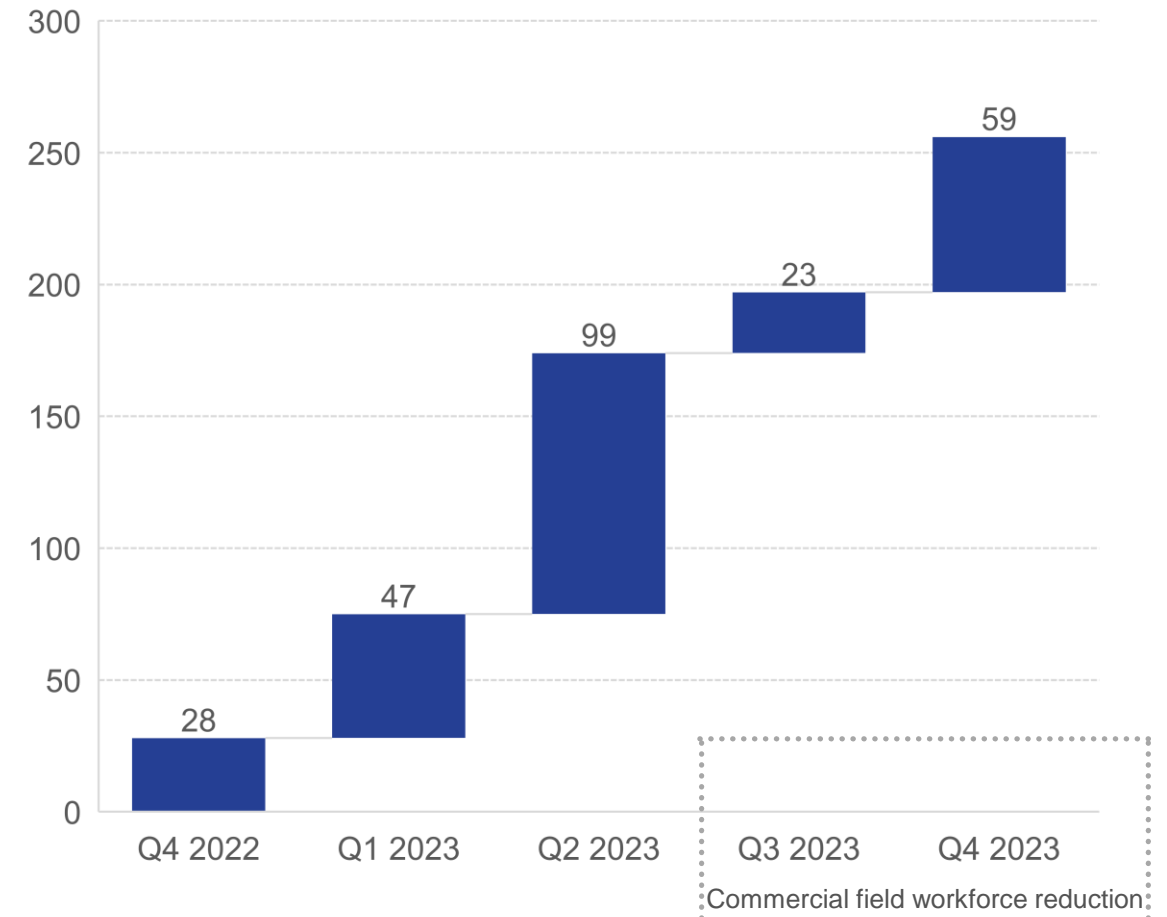
Please see Important Safety Information at the end of this presentation.

# Creating Demand in 2024

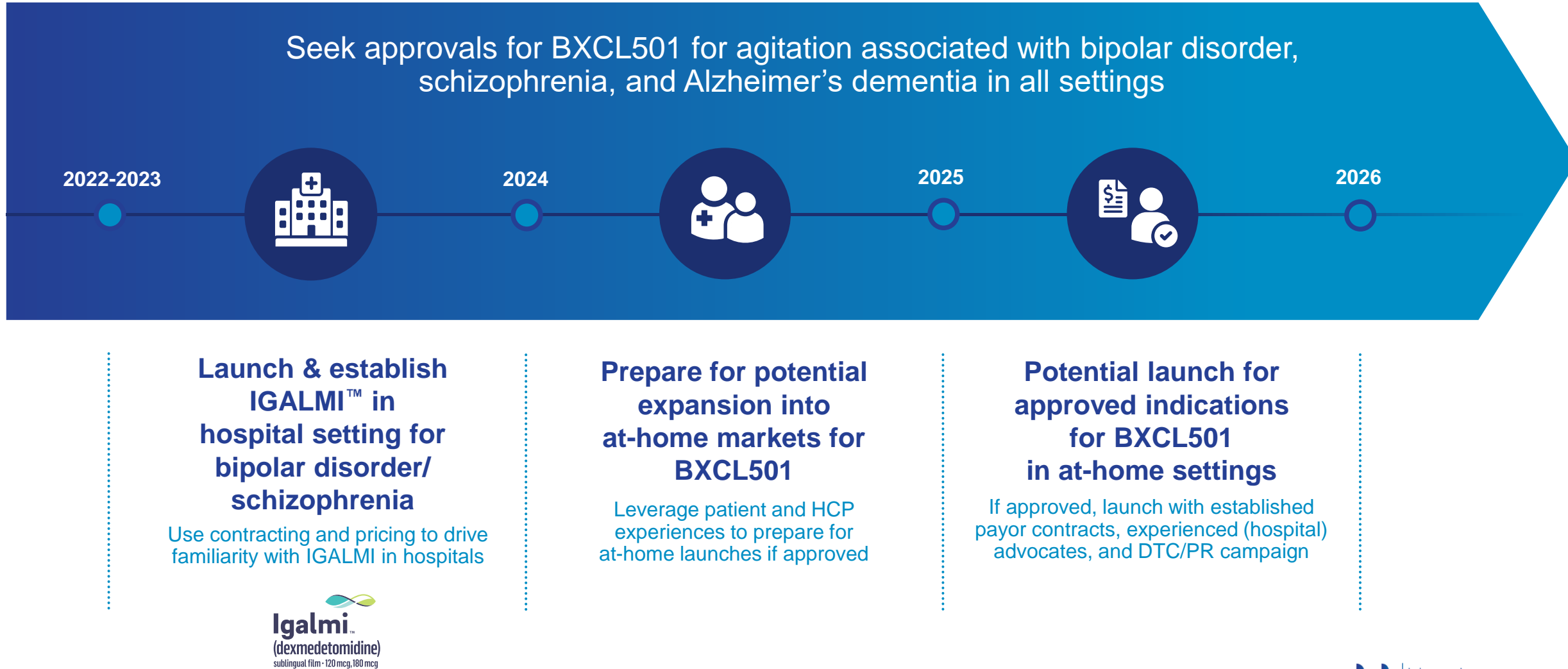
J-Code issuance, P&T formulary wins, and volume contracting to drive commercial progress following commercial field workforce reduction

- 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

## Formulary Wins



# Agitation Franchise Expansion Plan



# AI-Driven Drug Re-innovation Platform

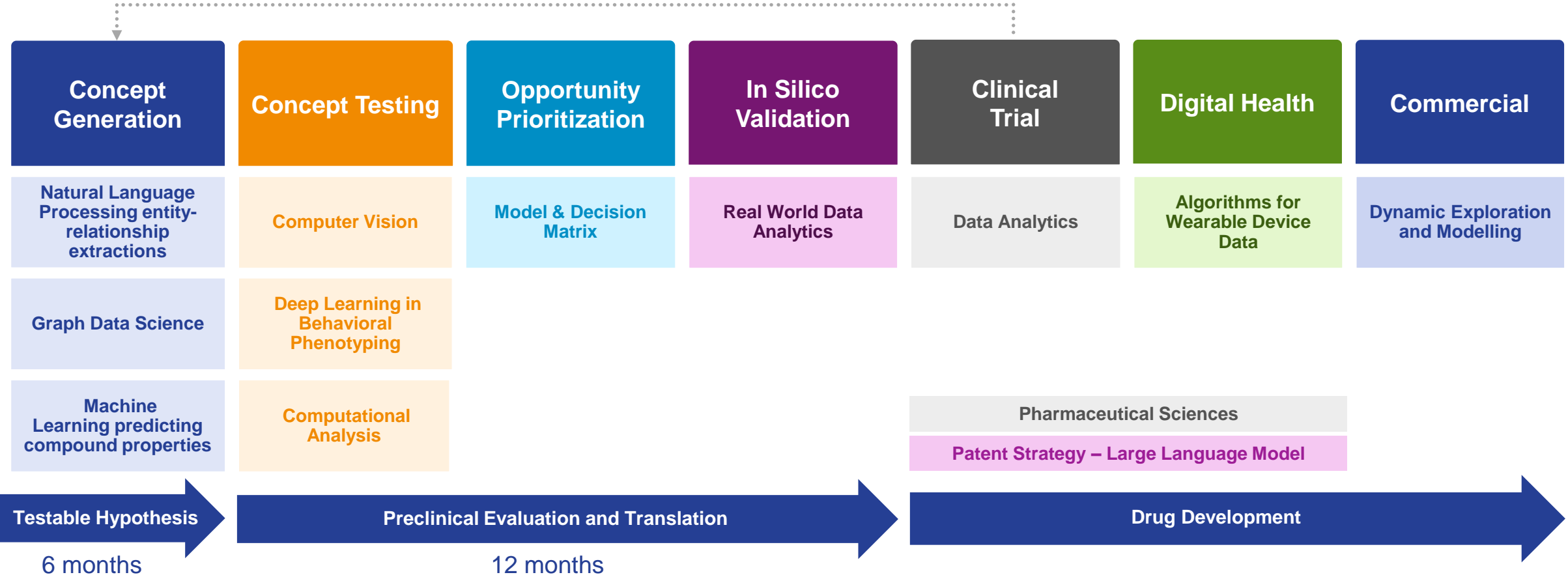
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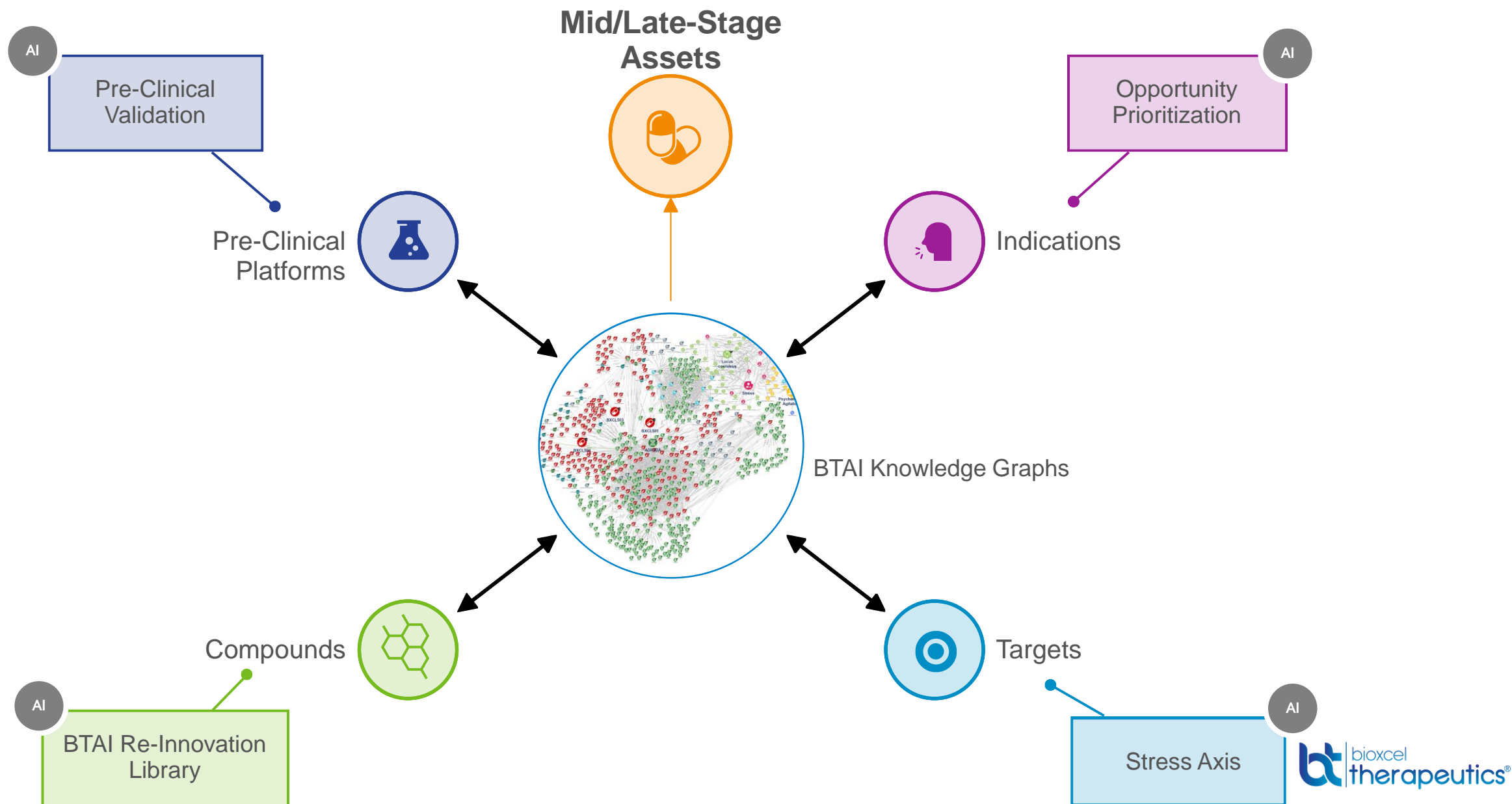
# AI Strategy to Accelerate Drug Re-Innovation Process

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

BioXcel Therapeutics AI and Analytics

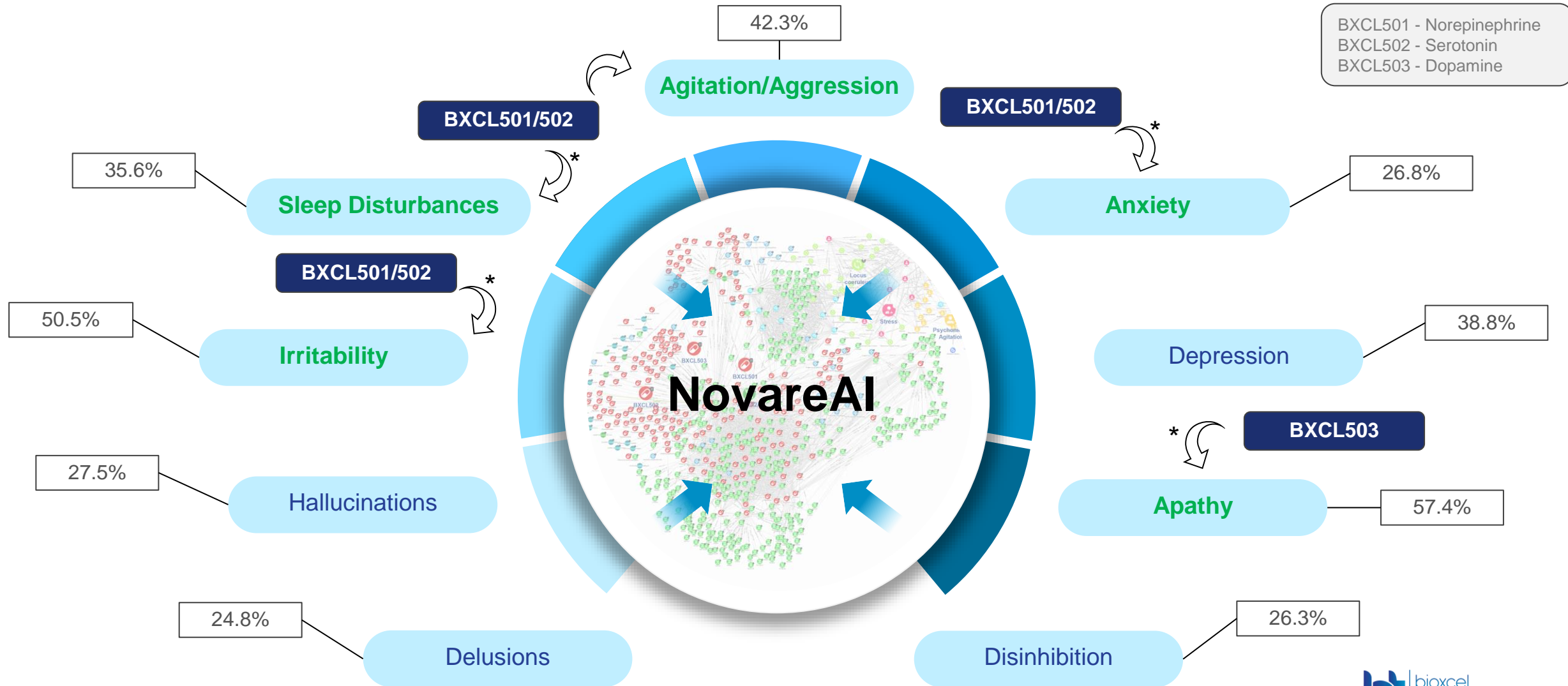


# NovareAI: Ecosystem for Drug Discovery and Development



# Behavioral and Psychological Symptoms in Alzheimer's Disease

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



\* 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**

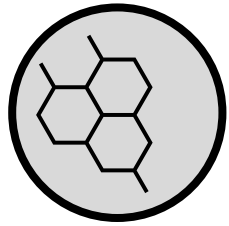
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# BXCL502 Presents a Compelling Value Proposition

Formulation studies are ongoing



**New Chemical Entity**

**BXCL502 is a novel formulation of latrepirdine and a metabolic stabilizer**



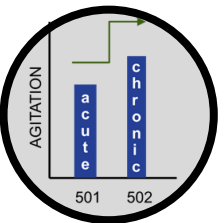
**Improved Understanding of Proposed Mechanism**

**Potentially blocks excessive signaling mediated by 2 neurotransmitters: serotonin and norepinephrine (noradrenaline)**



**Re-Innovation of Latrepirdine**

**Improved PK results suggest potential for once-daily dosing, which could be suitable for chronic agitation**

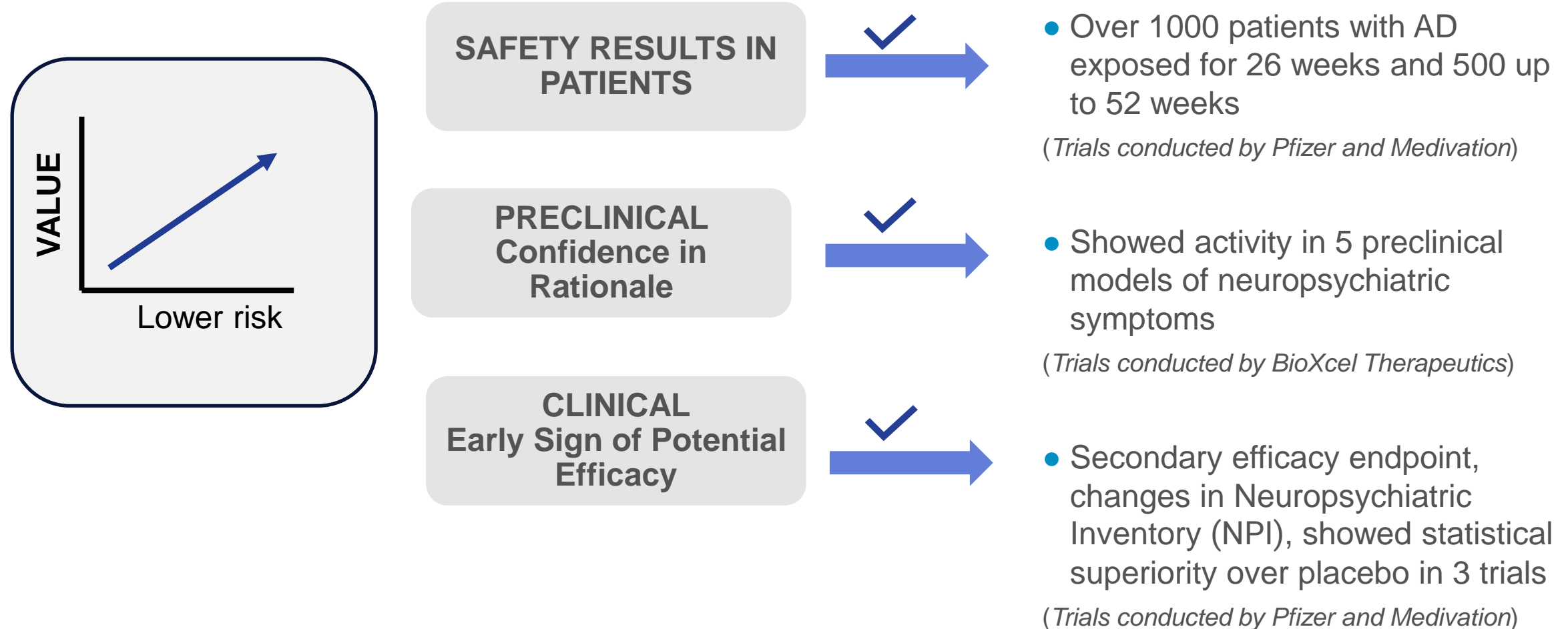


**Synergistic with Portfolio**

**Expanding agitation development programs from episodic to chronic**

# Latrepirdine (Dimebon): Clinical Safety Results, Preclinical Confidence in Rationale, and Early Sign of Potential Efficacy

Data support development for treatment of neuropsychiatric symptoms associated with dementia



# Recent Examples of Successful CNS Drug Re-Innovation

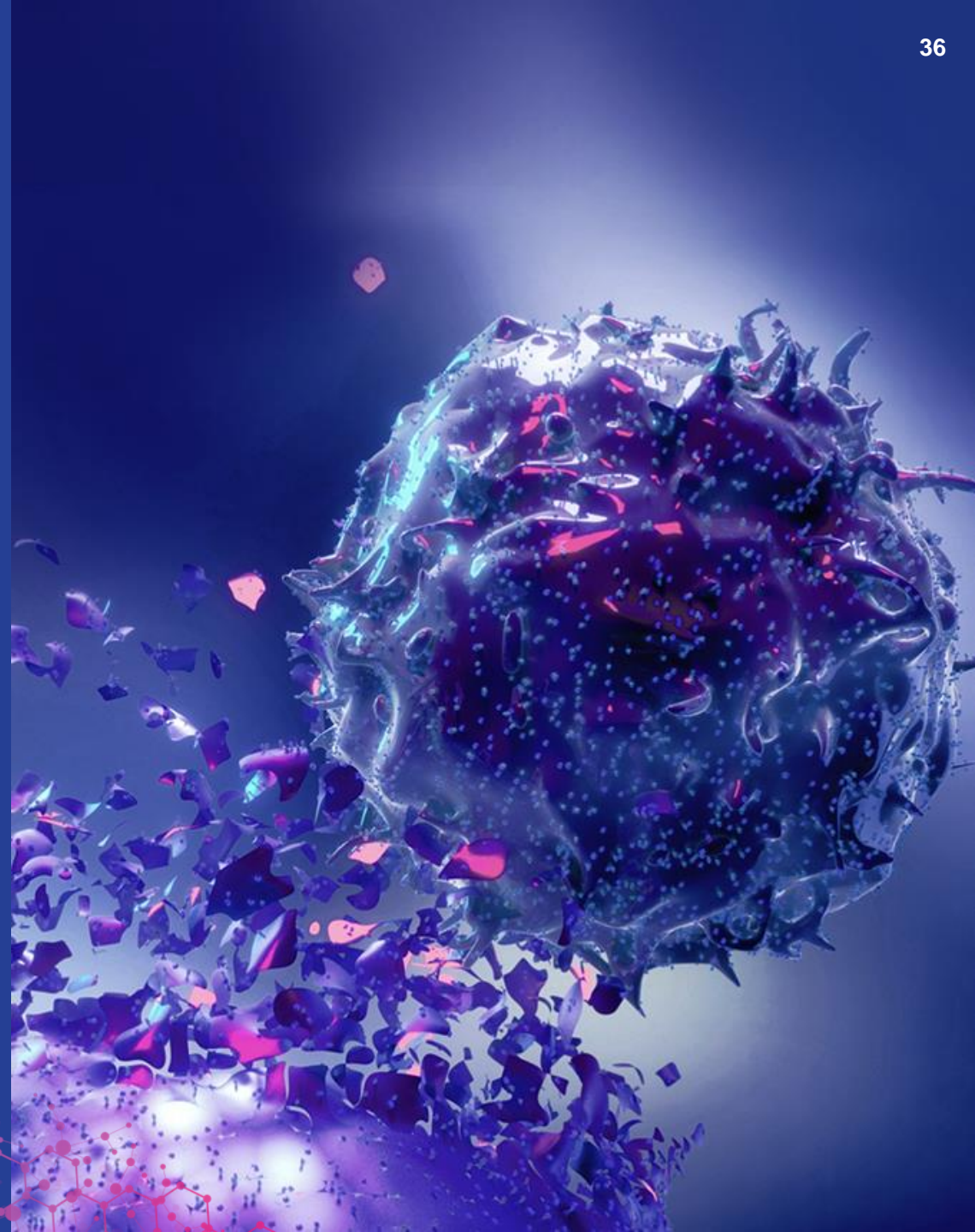
DRUG/COMPANY	CHALLENGE	SOLUTION	STATUS
Dextromethorphan Axxome Therapeutics	Metabolites cause unwanted side effects	Block metabolism with CYP2D6 inhibitor, bupropion	Successful clinical trial/depression
Xanomeline Karuna Therapeutics	Peripheral side effects	Block peripheral effects with trospium	Successful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

***Latrepirdine + “Metabolic Stabilizer” = BXCL502***

# Immuno-Oncology

## OnkosXcel Therapeutics™

A subsidiary of BioXcel Therapeutics, Inc.





# BXCL701: Strong Value Proposition in Hard-to-Treat Tumors

## Novel Mechanism of Action Data Published in JITC

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

## Clinical Proof of Concept Cold Tumors

- Positive results in two cold tumor types: mCRPC small cell neuroendocrine prostate cancer (SCNC) and adenocarcinoma
- Full Phase 2a data presented at PCF 2023
- 800+-subject clinical safety database

## Leadership Position in Innate Immunity DPP8/9 Biology

*FortySeven*  
acquired for ~\$5B  
by GILEAD



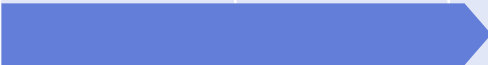


*Trillium*  
acquired for ~\$2.3B  
by Pfizer

Scarcity of assets  
in innate immunity

## Exploring Strategic Options

- Including potential financing, strategic partnership, or M&A

# Immuno-Oncology Clinical Development

Compound	Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Expected Upcoming Milestone	Collaborator
<b>BXCL701</b> Company-sponsored trials	Small Cell Neuroendocrine Prostate Cancer (SCNC)					FDA Meeting	13 centers US / UK
	Small Cell Lung Cancer (SCLC)					Initiate Phase 1b/2	
<b>BXCL701</b> Investigator-sponsored trials	Metastatic Pancreatic Ductal Adenocarcinoma					Phase 2 readout	Georgetown Lombardi Comprehensive Cancer Center Supply agreement: Merck
	Acute Myeloid Leukemia (AML)					Phase 1b readout	Dana-Farber Cancer Institute
<b>BXCL702</b> 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!

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# Appendix

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# 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 or behind the lower lip 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 been studied beyond 24 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 volume, diabetes, chronic 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 rate) and alertness 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 their healthcare 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, slow heart rate, low 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 torsades de pointes and 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 after taking IGALMI.
- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (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, dry mouth, low blood 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 blood pressure, 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 breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or [medinfo@bioxceltherapeutics.com](mailto:medinfo@bioxceltherapeutics.com).

**Please see full Prescribing Information.**