UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): April 10, 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 April 10, 2024, BioXcel Therapeutics, Inc. (the "Company" or "BioXcel") issued a presentation regarding the planned design of its upcoming TRANQUILITY In-Care Phase 3 trial. 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 Item 7.01 on 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 8.01. Other Events.

On April 10, 2024, the Company provided the following updates regarding the planned design of its upcoming TRANQUILITY In-Care Phase 3 trial to evaluate BXCL501, the Company's investigational proprietary, orally dissolving film formulation of dexmedetomidine, as a potential acute treatment for agitation associated with Alzheimer's dementia (AAD) in the care setting.

TRANQUILITY In-Care Pivotal Phase 3 Trial Design Summary

- The TRANQUILITY In-Care trial is designed as a double blind, placebo-controlled study to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 over a 12-week period.
- The trial is expected to enroll a total of approximately 150 patients 55 years and older across the spectrum of Alzheimer's disease severity with mild, moderate, and severe dementia with mini-mental state examination (MMSE) scores of 0 to 25 who reside in skilled nursing facilities, memory care units, or assisted living facilities.
- The trial is expected to enroll patients with episodic agitation with patients self-administering 60 mcg of BXCL501 or placebo when agitation episodes occur over the trial period.
- The primary endpoint is expected to be a change from baseline in the Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score at two hours post-first dose. This is the same endpoint used in previous TRANQUILITY trials and in studies that supported the FDA approval of IGALMI™ (dexmedetomidine) sublingual film.
- Continued efficacy evaluations are expected to be conducted through performing additional PEC and complementary efficacy measures, including the global impression of change in agitation.
- As part of the TRANQUILITY In-Care trial, the Company plans to include a feasibility cohort of 20 patients that would be evaluated in the home setting.

The Company expects to generate additional Phase 3 efficacy and safety data in the TRANQUILITY In-Care trial to expand the database beyond the 70 patients who have already been treated with 60 mcg of BXCL501 in TRANQUILITY I and II to date. The Company also plans to discuss the details of the requirement for long-term safety data at a future meeting with the FDA.

Forward-Looking Statements

This Current Report on Form 8-K ("Form 8-K") includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Form 8-K other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the planned trial design of the TRANQUILITY In-Care trial; expected discussions with the FDA; and the potential for the results from the Company's completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates in both the care-facility and at-home settings. When used herein, words including "anticipate," "believe," "can," "continue," "could," "designed," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. 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 the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company 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 and limited revenue generation; its incurrence of significant losses; its strategic reprioritization and related reduction in force may not achieve its intended outcome; its need for substantial additional funding and ability to raise capital when needed; its significant indebtedness, ability to comply with covenant obligations and potential payment obligations related to such indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY program; risks related to the limited clinical data supporting potential safety or efficacy of BXCL501 for use in the at-home setting; its dependence on the success and commercialization of IGALMI, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; interim "top-line" and preliminary data from its clinical trials may change and result in material changes in the final data; its ability to receive regulatory approval from the FDA and comparable foreign authorities for its product candidates; clinical trials are expensive, time-consuming, difficult to design, difficult to conduct, and involve an uncertain income; its lack of experience in marketing and selling drug products; the risk that IGALMI or the Company's product candidates may not be accepted by physicians or the medical community in general; the Company's estimated number of episodes of agitation and its corresponding estimated total addressable market are subject to inherent challenges and uncertainties; the Company still faces extensive and ongoing regulatory requirements and obligations for IGALMI; 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 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; the significant influence of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from data breaches or cyber-attacks, if any; the Company is and may in the future be subject to legal proceedings, claims and investigations in or outside the ordinary course of business, which could be costly and time-consuming to defend and could result in unfavorable outcomes; risks related to unfavorable global political or economic events and conditions; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; risks associated with federal, state or foreign health care "fraud and abuse" laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors section of the Company's website at www.bioxceltherapeutics.com. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. While the Company 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 the Company's views as of any date subsequent to the date of this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	BioXcel Therapeutics, Inc. April 10, 2024 Presentation
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: April 10, 2024

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
By: Richard Steinhart
Title: Chief Financial Officer

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

TRANQUILITY Program

April 10, 2024

Forward-Looking Statements

This presentation includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. BioXcel Therapeutics, Inc. (“BioXcel” or the “Company”) statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securit amended. All statements contained in this presentation other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements relat regulatory and clinical design or progress, potential regulatory submissions, approvals and timing thereof for BXCL501 as a potential acute treatment for AAD; developments and plans relating t and the potential for the results from the Company’s completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates in both the care-facility and at-hom words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “shou similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. In addition, any statements or information tha plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking sta Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

The Company 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 a factors, including, without limitation: its limited operating history and limited revenue generation; its incurrence of significant losses; its strategic reprioritization and related reduction in force outcome; its need for substantial additional funding and ability to raise capital when needed; its significant indebtedness, ability to comply with covenant obligations and potential payme indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experien development; risks related to the TRANQUILITY program; risks related to the limited clinical data supporting potential safety or efficacy of BXCL501 for use in the at-home setting; its dep commercialization of IGALMI, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; interim “top-line” and preliminary data from its clinical trials may change and result i data; its ability to receive regulatory approval from the FDA and comparable foreign authorities for its product candidates; clinical trials are expensive, time-consuming, difficult to design, diffi uncertain income; its lack of experience in marketing and selling drug products; the risk that IGALMI or the Company’s product candidates may not be accepted by physicians or the medi Company’s estimated number of episodes of agitation and its corresponding estimated total addressable market are subject to inherent challenges and uncertainties; the Company still faces ext requirements and obligations for IGALMI; 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 futu 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 Evo of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from dat any; the Company is and may in the future be subject to legal proceedings, claims and investigations in or outside the ordinary course of business, which could be costly and time-consuming unfavorable outcomes; risks related to unfavorable global political or economic events and conditions; risks associated with the increased scrutiny relating to environmental, social and gov associated with federal, state or foreign health care “fraud and abuse” laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the capti Report on Form 10-K for the fiscal year ended December 31, 2023, which are accessible on the SEC’s website at www.sec.gov and the Investors section of the Company’s website at www.bioxc 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 repre as of the date of this presentation. While the Company 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 cause the Company’s views to change. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this presentatio

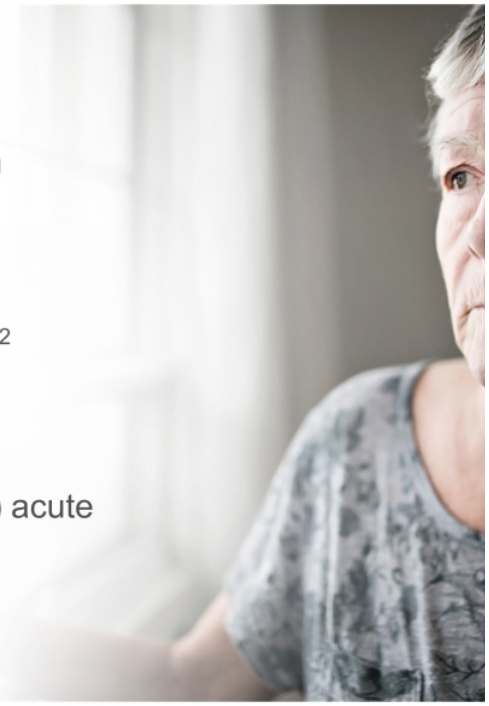
INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this presentation concerning our industry and the markets in which BioXcel Therapeutics operates, including its general expectations, market p opportunity, is based on its management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. While BioXcel Thera information from these third-party publications, research, surveys and studies is reliable, it does not guarantee the accuracy or completeness of such information, and BioXcel Therapeutics has no information. Management’s estimates are derived from publicly available information, their knowledge of the company's industry and their assumptions based on such information and knowledge, reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described periodic reports filed with the SEC under the captions “Forward Looking Statements,” "Risk Factor Summary" and “Risk Factors.” These and other factors could cause BioXcel Therapeutics' future expectations to differ materially from its assumptions and estimates.

AAD is Debilitating for Patients and a Burden for Caregive

Agitation cited as a top driver in deciding to move a patient from home setting to residen

- Nearly 7 million Alzheimer's dementia patients in the U.S., with approximately 50% suffering from agitation.[2]
- AD-related agitation typically worsens over time[2]
  - Both the number and severity of agitation episodes increase[2]
  - Often places significant burden on caregivers[1,2]
- No FDA-approved therapeutic options for an as-needed (PRN) acute treatment of agitation in Alzheimer's patients[3]



1. Data on File InVibe Patient and Caregiver Research (n=75) December 2022
2. 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.; 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.
3. Joint Meeting of the Psychopharmacologic and the Peripheral and Central Nervous System Drugs Advisory Committee Meeting April 14th, 2023

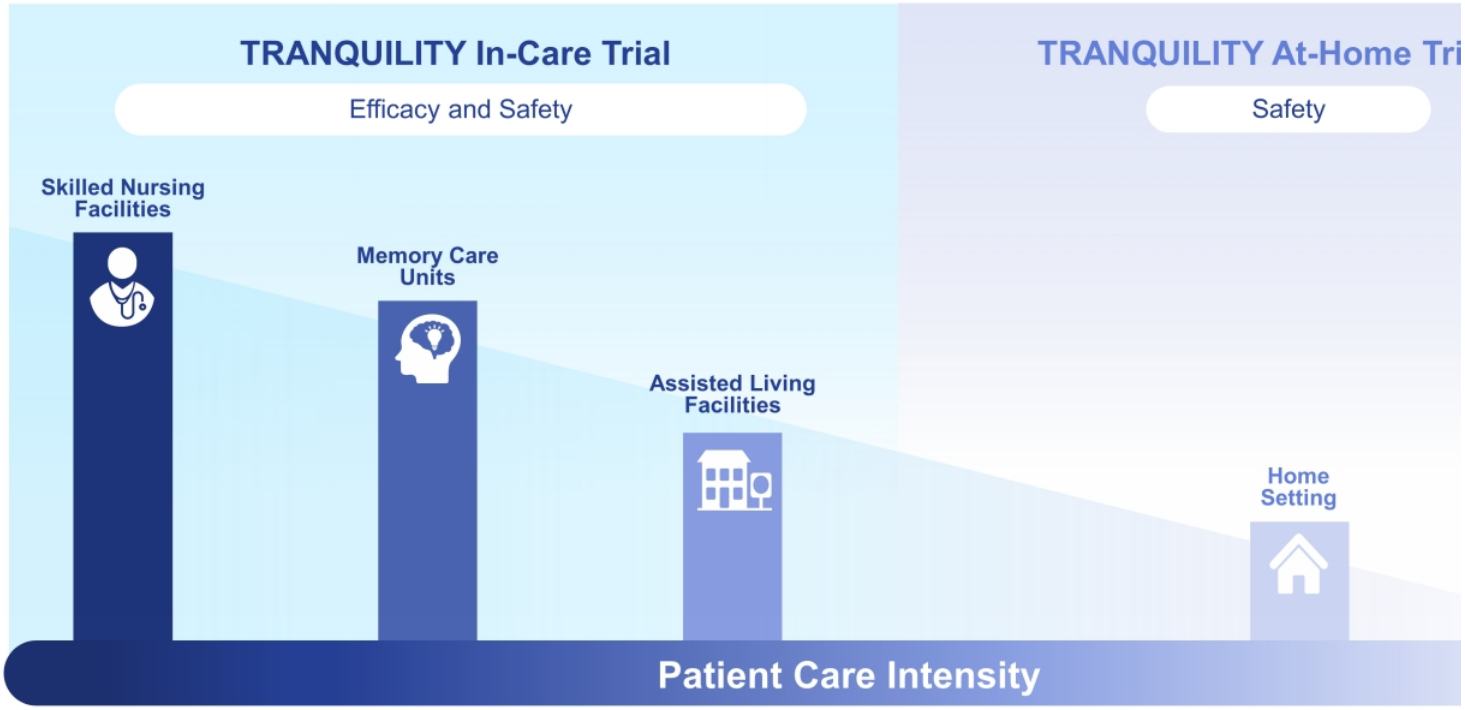
TRANQUILITY Program Offers Potential Path to sNDA

- Plan to discuss details of requirement for long-term safety data at future meeting with FDA**
- Company has developed preliminary TRANQUILITY At-Home trial design and is re-evaluating

* Trial protocol under development, design may be subject to change.
** Per ICH guidelines, the Company may be required to collect 6-month safety data from at least 300 patients and 1-year safety data from at least 100 patients prior to submitting any sNDA

Evaluating BXCL501 for AAD in High to Low Care Settings

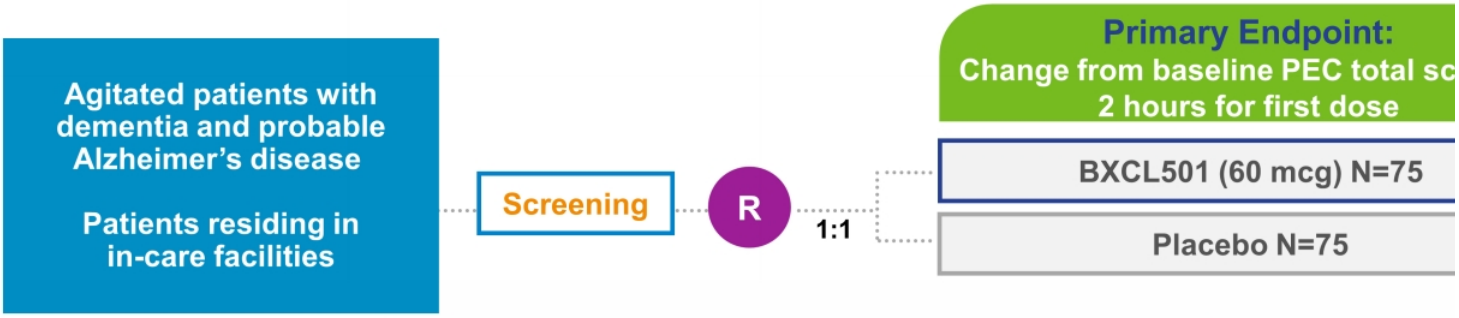
Clinical trial strategy designed to maximize potential commercial opportunity across pati



*Trial design may be subject to change

Skilled-Nursing Facilities: medical setting for patients with advanced health conditions who receive 24/7 skilled nursing care and medical monitoring
Memory Care Units: medical setting for patients with dementia who receive specialized care for symptom management
Assisted Living Facilities: residential setting for elderly patients who are largely independent but need help with ADLs (bathing, dressing, and other non-medical type assistance)

TRANQUILITY In-Care Study Design*

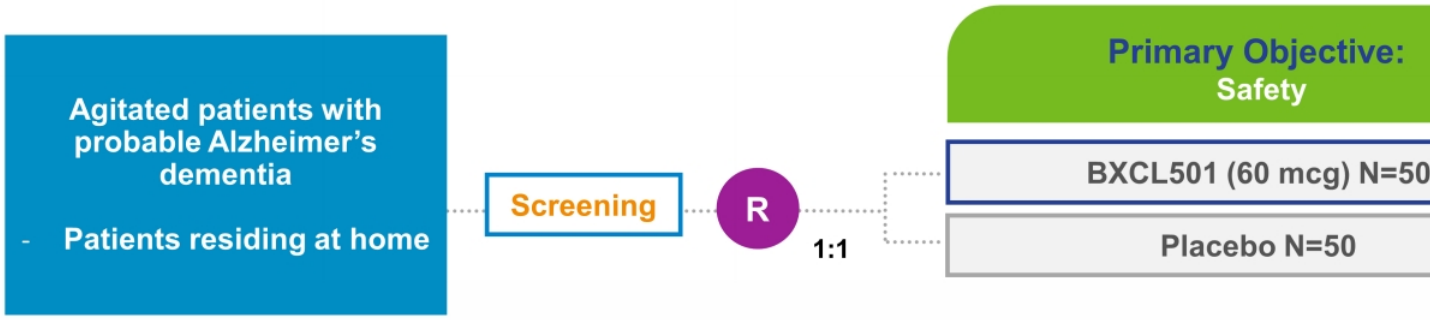


Feasibility cohort of 20 patients for at-home setting**

- **Design:** Randomized, double-blind, placebo-controlled, parallel group trial
- **Power:** Over 80% power
- **Inclusion Criteria**
  - Patients with probable AD (mild, moderate, or severe, MMSE ≤ 25), who experience agitation, and residing in skilled nur memory care units, or assisted living facilities
  - Patients with episodes of agitation in the month prior to enrollment
  - PEC total score ≥14 prior to randomization
- **Primary Endpoint:** Change from baseline of PEC total score at 2 hours for **first dose**
- **Study Duration:** 12 weeks with assessment of continued efficacy (up to 3 PECs)

*For illustrative purposes only: protocol under development and trial design may be subject to change. The FDA has not provided feedback on this trial.
** Represents a separate cohort of 20 patients who reside at home in addition to the 150 patients who are in care facilities

Preliminary TRANQUILITY At-Home Study Design*



- **Study Design:** Randomized, double-blind, placebo-controlled, parallel group trial
- **Primary Objective:** Safety and tolerability of BXCL501 60 mcg
- **Inclusion Criteria**
  - Patients with mild, moderate, or severe probable AD who experience agitation, MMSE ≤ 25
  - Patients with **not more than three episodes of agitation per week** in the month prior to enrollment
  - Patients with caregivers
- **Treatment**
  - BXCL501 60 mcg or placebo administered for agitation in at-home setting

* For illustrative purposes only. Protocol under development and trial design may be subject to change. The FDA has not provided feedback on this trial.

Thank you!

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