UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KATELYN MARTIN, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. BIOXCEL THERAPEUTICS, INC., VIMAL MEHTA, and RICHARD STEINHART, Defendants.	Case No. JURY TRIAL DEMANDED July 7, 2023

CLASS ACTION COMPLAINT

Introduction

1. Plaintiff Katelyn Martin ("Plaintiff"), individually and on behalf of all others similarly situated, by and through her attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, her counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by BioXcel Therapeutics, Inc. ("BioXcel" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by BioXcel; and (c) review of other publicly available information concerning BioXcel.

NATURE OF THE ACTION AND OVERVIEW

2. This is a class action on behalf of persons and entities that purchased or otherwise acquired BioXcel securities between December 15, 2021 and June 28, 2023, inclusive (the "Class

Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

3. BioXcel is a biopharmaceutical company that claims it uses artificial intelligence ("AI") approaches to develop medicines in neuroscience and immuno-oncology. The Company states that it leverages existing approved drugs and clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. BioXcel claims that its most advanced clinical development program is BXCL501, which is purportedly a proprietary, orally dissolving, film formulation of dexmedetomidine (or "Dex") for the treatment of agitation associated with psychiatric and neurological disorders.

4. On December 15, 2021, the Company announced that it had initiated a program to evaluate BXCL501 for the treatment of acute agitation associated with Alzheimer's disease. The Company announced that the program consisted of two randomized, double-blind, placebo-controlled studies: TRANQUILITY II and TRANQUILITY III. The studies were purportedly designed to evaluate the safety and efficacy of BXCL501 in adults 65 years and older across the range of illness including mild, moderate, and severe dementia in assisted living or residential facilities and nursing homes.

5. However, on June 29, 2023, before the market opened, BioXcel disclosed that its principal investigator for the Phase 3 TRANQUILITY II clinical trial had failed to "adhere to the informed consent form approved by the Institutional Review Board" for some subjects and failed to maintain adequate case histories for certain patients whose records were reviewed by the Food and Drug Administration ("FDA"). The Company further disclosed that the same principal investigator "may have fabricated" email correspondence purporting to demonstrate that the investigator timely submitted to the Company's pharmacovigilance safety vendor a report of a

serious adverse event ("SAE") and purporting to show that the vendor had confirmed receipt. BioXcel further disclosed that the fabricated email correspondence was provided to the FDA during an on-site inspection in December 2022. The Company further disclosed that it was in the process of conducting an investigation into protocol adherence and data integrity at the principal investigator's trial site and was in the process of retaining an independent third party to audit the data collected at the site. The Company also disclosed that the foregoing "may impact the timing of the Company's development plans for, and prospects for regulatory approval of, BXCL501 for the acute treatment of agitation associated with dementia in patients with probable Alzheimer's disease."

6. On this news, BioXcel's stock price fell $11.28 per share, or 63.8%, to close at $6.39 per share on June 29, 2023, on unusually heavy trading volume.

7. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company lacked adequate internal controls over protocol adherence and data integrity; (2) that, as a result, the Company's principal investigator failed to adhere to the informed consent form approved by the Institutional Review Board; (3) that the Company's principal investigator failed to maintain adequate case histories for certain patients whose records were reviewed by the FDA; (4) that the Company's principal investigator fabricated email correspondence with a pharmacovigilance safety vendor that was then provided to the FDA; (5) that the foregoing would negatively impact the Company's ability to obtain regulatory approval of BXCL501 for the treatment of agitation associated with dementia in patients with probable Alzheimer's disease; and

(6) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

12. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

13. Plaintiff Katelyn Martin, as set forth in the accompanying certification, incorporated by reference herein, purchased BioXcel securities during the Class Period, and

suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

14. Defendant BioXcel is incorporated under the laws of Delaware with its principal executive offices located in New Haven, Connecticut. BioXcel's common stock trades on the NASDAQ stock market under the symbol "BTAI."

15. Defendant Vimal Mehta ("Mehta") was the President and Chief Executive Officer ("CEO") of BioXcel at all relevant times.

16. Defendant Richard Steinhart ("Steinhart") was the Chief Financial Officer ("CFO") of BioXcel at all relevant times.

17. Defendants Mehta and Steinhart (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

18. BioXcel is a biopharmaceutical company that claims it uses AI approaches to develop medicines in neuroscience and immuno-oncology. The Company states that it leverages

existing approved drugs and clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. BioXcel claims that its most advanced clinical development program is BXCL501, which is purportedly a proprietary, orally dissolving, film formulation of Dex for the treatment of agitation associated with psychiatric and neurological disorders.

19. On December 15, 2021, the Company announced that it had initiated a program to evaluate BXCL501 for the treatment of acute agitation associated with Alzheimer's disease. The Company announced that the program consisted of two randomized, double-blind, placebo-controlled studies: TRANQUILITY II and TRANQUILITY III. The studies were purportedly designed to evaluate the safety and efficacy of BXCL501 in adults 65 years and older across the range of illness including mild, moderate, and severe dementia in assisted living or residential facilities and nursing homes.

Materially False and Misleading
Statements Issued During the Class Period

20. The Class Period begins on December 15, 2021. On that day, BioXcel issued a press release titled "BioXcel Therapeutics Initiates Pivotal Phase 3 Program of BXCL501 for Acute Treatment of Agitation in Patients with Alzheimer's Disease." Therein, the Company, in relevant part, stated:

> BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced the initiation of its pivotal Phase 3 program for BXCL501, the Company's proprietary, orally dissolving thin film formulation of dexmedetomidine, for the acute treatment of agitation in patients with Alzheimer's disease (AD). The program's two studies, TRANQUILITY II and TRANQUILITY III, are designed to evaluate the safety and efficacy of BXCL501 in adults 65 years and older in assisted living or residential facilities and nursing homes.
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> "We received FDA breakthrough therapy designation for BXCL501 in March 2021 based on our Phase 1b/2 TRANQUILITY study. Following multiple meetings with

the FDA, we are pleased to announce the initiation of our Phase 3 program," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "This marks an important advancement in potentially bringing this novel treatment to the more than 4 million patients, who experience agitation as one of AD's most devastating symptoms. We are leading the development path for this innovative therapy and are confident in BXCL501's potential to treat acute, as well as intermittent, forms of agitation."

The program expands the evaluation of patients in diverse medical settings across the range of dementia severity. It is designed to maximize the opportunity of BXCL501 for the treatment of the full spectrum of agitation associated with AD.

Pivotal Phase 3 Program Summary

- The program will consist of two randomized, placebo-controlled, adaptive, parallel group pivotal trials, TRANQUILITY II and TRANQUILITY III.

- Each study will enroll 150 dementia patients 65 years and older. Patients will self-administer 40 mcg or 60 mcg of BXCL501 or placebo whenever agitation episodes occur over a three-month period.

- TRANQUILITY II will enroll patients in assisted living or residential facilities requiring minimal assistance with activities of daily living. TRANQUILITY III will enroll patients in nursing homes with moderate to severe dementia requiring moderate or greater assistance with activities of daily living.

- The studies are designed to assess agitation as measured by the changes from baseline in the Positive and Negative Syndrome Scale-Excitatory Component (PEC) and Pittsburgh Agitation Scale (PAS) total scores. The primary efficacy endpoint for both studies will be change in PEC score from baseline measured at two hours after the initial dose and subsequent doses.

- Patients who complete TRANQUILITY II or TRANQUILITY III will be eligible to enroll in an open label, 52-week safety study designed to measure the safety and efficacy of BXCL501 in continued use.

21. On May 3, 2022, BioXcel issued a press release titled "BioXcel Therapeutics Announces First Patient Dosed in TRANQUILITY II Phase 3 Trial for Acute Treatment of Agitation in Patients with Alzheimer's Disease." Therein, the Company, in relevant part, stated:

> BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a commercial-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced the first patient has been dosed in the Phase 3 TRANQUILITY II study of

> BXCL501, the Company's proprietary, orally dissolving thin film formulation of dexmedetomidine, for the acute treatment of agitation in patients with Alzheimer's disease (AD). The pivotal Phase 3 TRANQUILITY program includes two studies, TRANQUILITY II and TRANQUILITY III, which are designed to evaluate the safety and efficacy of BXCL501 in adults 65 years and older in assisted living or residential facilities and nursing homes.
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> "There are an estimated 100 million agitation episodes annually in the U.S. associated with Alzheimer's disease1, which have a devastating impact on patients and their caregivers," said Robert Risinger, M.D., Chief Medical Officer of BioXcel Therapeutics. "We believe the recent FDA approval of BXCL501 for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults has laid a strong foundation for pursuing this Alzheimer's-related agitation program to potentially address this debilitating symptom for patients. Importantly, we are also expanding TRANQUILITY II to more than 10 clinical trial sites in the U.S. and with no current FDA approved treatments for agitation associated with this disease, we are making strong and swift efforts to potentially bring BXCL501 and its proven ability to address agitation to this large market."
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> The Company's decision to continue the evaluation of both the 40 and 60 mcg dosing regimens in the TRANQUILITY II and III pivotal trials is further supported by results from a recent 46 patient, multicenter, placebo-controlled study evaluating the efficacy, safety and tolerability of BXCL501 40 mcg dose in patients with agitation associated with dementia. Previously, BXCL501 was granted Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the acute treatment of agitation associated with dementia. BXCL501 demonstrated statistically significant reductions in agitation measures with both the 30 and 60 mcg doses as measured by multiple scales with no severe or serious adverse events.

22. On August 9, 2022, BioXcel issued a press release titled "BioXcel Therapeutics Reports Second Quarter 2022 Financial Results and Recent Operational Highlights." Therein, the Company, in relevant part, stated:

> BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a commercial-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its financial results for the second quarter ended June 30, 2022 and provided an update on key strategic initiatives.
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> "BioXcel Therapeutics made tremendous progress in its journey to becoming a fully integrated AI-driven commercial-stage company with the potential to transform the agitation treatment landscape," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "This transformation is being driven by the continued

execution of our land and expand strategy within our neuroscience franchise. We are focused on the commercial launch for our recently FDA approved drug IGALMI™ while significantly increasing the opportunity for BXCL501 through at-home, medical setting expansion and the pursuit of multiple additional indications for our BXCL501 franchise. We believe we are well-positioned and have laid a strong foundation to drive long-term sustainable growth."

* * *

Clinical Pipeline

BXCL501, a proprietary, sublingual film formulation of dexmedetomidine, has received Breakthrough Therapy and Fast Track designation for the acute treatment of agitation associated with dementia.

Indication Expansion

- Alzheimer's Disease-related Agitation: TRANQUILITY program is designed to capture Alzheimer's-related agitation market opportunity. There are an estimated 100 million agitation episodes in Alzheimer's patients occurring in the U.S. annually.
    - TRANQUILITY II: top-line data readout expected in 1H 2023.
    - TRANQUILITY III: enrollment expected to begin in 2H 2022.

23. On November 10, 2022, BioXcel issued a press release titled "BioXcel Therapeutics Reports Third Quarter 2022 Financial Results and Recent Operational Highlights." Therein, the Company, in relevant part, stated:

BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its financial results for the third quarter ended September 30, 2022 and provided an update on key strategic initiatives.

"In the four months since IGALMI's trade launch, BioXcel Therapeutics is advancing its leadership position in the agitation-treatment market," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "In parallel, we are anticipating pivotal trial data readouts investigating BXCL501 for the treatment of Alzheimer's-related agitation, and bipolar and schizophrenia-related agitation in an at-home setting. We are well-positioned to potentially capture 139 million annual agitation episodes in the U.S.1-5 Our company is rooted in AI-driven innovation, and we are

proud to be at the forefront of developing transformative medicines in neuroscience."

* * *

Clinical Pipeline

BXCL501, a proprietary, sublingual film formulation of dexmedetomidine, has received Breakthrough Therapy and Fast Track designation for the acute treatment of agitation associated with dementia.

- **Alzheimer's Disease-related Agitation:** TRANQUILITY program is designed to evaluate BXCL501 in Alzheimer's-related agitation, where 100 million agitation episodes are estimated to occur in the U.S. annually.
    - TRANQUILITY II: On track to announce top-line data in 1H 2023.
    - TRANQUILITY III: Expect to initiate enrollment in December 2022.
    - Independent Data and Safety Monitoring (DSM) committee periodically reviews subject safety and tolerability, recommending study continuation.

(Footnote omitted.)

24. On December 19, 2022, BioXcel issued a press release titled "BioXcel Therapeutics Announces First Patient Dosed in TRANQUILITY III Phase 3 Trial for Acute Treatment of Agitation in Patients with Alzheimer's Disease." Therein, the Company, in relevant part, stated:

BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced that the first patient has been dosed in the pivotal Phase 3 TRANQUILITY III trial of BXCL501 (dexmedetomidine) sublingual film, the Company's proprietary, orally dissolving film, under investigation for the acute treatment of agitation in patients with Alzheimer's disease (AD). AD is the most prevalent type of dementia in the U.S.5 The TRANQUILITY program includes two investigational studies, TRANQUILITY II and TRANQUILITY III, which are designed to evaluate the safety and efficacy of BXCL501 for the acute treatment of Alzheimer's-associated agitation in adults 65 years and older in assisted living or residential care facilities and nursing homes.

"The prevalence of Alzheimer's disease is unfortunately increasing and there remains no FDA-approved product indicated for patients experiencing agitation

> associated with this condition," said Robert Risinger, M.D., Chief Medical Officer, Neuroscience of BioXcel Therapeutics. "With two pivotal trials underway in our TRANQUILITY program, we are aiming to expand BXCL501's potential to treat the full spectrum of episodic and intermittent chronic agitation market, and address the costly health-care burden related to Alzheimer's agitation."
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> There are approximately 100 million reported agitation episodes that occur in the U.S. each year related to Alzheimer's disease.1 The number of adults over the age of 65 with AD is expected to double from 5.8 million in 2020 to 11.8 million in 2040 6, representing a significant and growing market opportunity for BXCL501. This potential opportunity is in addition to the current acute treatment of agitation associated with schizophrenia or bipolar I or II disorder market opportunity. Approximately 16 million episodes of schizophrenia and bipolar disorder-associated agitation occur in institutional settings and, when combined with at-home episodes, 23 million annually in the U.S.2-4
>
> TRANQUILITY II and III will evaluate the safety and efficacy of BXCL501 in patients who experience agitation across diverse settings and across the range of dementia severity. Each trial will enroll approximately 150 patients with dementia ages 65 years and older who will self-administer 40mcg or 60mcg of BXCL501 or placebo under the supervision of a trained research staff member whenever agitation episodes occur over a three-month period. TRANQUILITY II will assess patients in assisted living or residential care facilities requiring minimal assistance with activities of daily living. TRANQUILITY III will assess patients residing predominantly in nursing homes with moderate to severe dementia who require moderate or greater assistance with activities of daily living. The primary efficacy endpoint for both studies is change in Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score from baseline measured at two hours after the initial dose and subsequent doses.

25. On March 9, 2023, BioXcel issued a press release titled "BioXcel Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Operational Highlights."

Therein, the Company, in relevant part, stated:

> BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its financial results for the fourth quarter and full year ended Dec. 31, 2022 and provided an update on key strategic initiatives.
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> "Last year was a transformational period for the Company, highlighted by the launch of our first AI-discovered commercial product, IGALMI, in under four years since initiating human trials. A new treatment option is now available for patients suffering from agitation associated with schizophrenia or bipolar I or II disorder,"

said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "We are building on these achievements in 2023 and look to accelerate our growth through commercial execution of IGALMI. We are also on track for significant data readouts for our overall neuropsychiatric program that has potential to address an estimated 139 million agitation episodes in the U.S.1-3* We have two pivotal study readouts for BXCL501 expected in the second quarter of 2023. Lastly, we plan to advance our lead immuno-oncology program, BXCL701, into a Phase 2b registrational trial, pending further discussion with the FDA, in conjunction with exploring strategic options for our OnkosXcel subsidiary. These upcoming milestones, along with our strong financial foundation and late-stage programs, position BioXcel Therapeutics to deliver significant value to our shareholders while helping treat millions of patients."

* * *

Development Pipeline
BXCL501, a proprietary, sublingual film formulation of dexmedetomidine, has received Breakthrough Therapy and Fast Track designation for the acute treatment of agitation associated with dementia.

- **Alzheimer's Disease-related Agitation:** TRANQUILITY program is designed to evaluate BXCL501 for the acute treatment of Alzheimer's-related agitation, where up to 100 million agitation episodes are estimated to occur in the U.S. annually.
    - TRANQUILITY II: Trial is fully enrolled; nearing completion of three-month observation period in a few patients in assisted living facilities (ALFs) and residential settings.
        - Data cleaning and verification in progress.
        - Top-line data from pivotal trial expected in Q2 2023.
    - TRANQUILITY III: Continuing enrollment of patients with moderate to severe dementia in nursing homes.

(Footnote omitted.)

26. On May 8, 2023, BioXcel issued a press release titled "BioXcel Therapeutics Reports First Quarter 2023 Financial Results and Recent Operational Highlights." Therein, the Company, in relevant part, stated:

BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in

neuroscience and immuno-oncology, today announced its financial results for the first quarter ended March 31, 2023, and provided an update on key strategic initiatives.

"The first quarter marked a strong start to the year with numerous advancements in our clinical programs and continued commercial focus building the agitation market for our new therapeutic option in a historically underdiagnosed and underserved medical condition," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "We are gearing up to announce top-line data readouts in agitation from two Phase 3 pivotal trials as well as BXCL501 potential as an adjunctive treatment for chronic use in our MDD program. In addition, IGALMI's launch momentum is expanding our reach into addressable market opportunities. We believe the second quarter of 2023 represents a defining moment for the Company as we expand the full potential of BXCL501 in agitation for at-home use and long-term care settings, and in depression. These upcoming catalysts may have a transformational impact for patients in need and all our stakeholders."

* * *

Development Pipeline
BXCL501, an investigational proprietary, sublingual film formulation of dexmedetomidine, has received Breakthrough Therapy and Fast Track designation for the acute treatment of agitation associated with dementia.

- **Alzheimer's Disease-related Agitation:** TRANQUILITY program is designed to evaluate BXCL501 for the acute treatment of Alzheimer's-related agitation; up to 100 million Alzheimer's-related agitation episodes are estimated to occur in the U.S. annually.
    - TRANQUILITY II: Trial is fully enrolled, and all patients have completed the study in assisted living facilities (ALFs) and residential care settings.
        - Data cleaning and verification in progress.
        - Top-line data from pivotal trial expected in June 2023.
    - TRANQUILITY III: Continuing enrollment of patients with moderate to severe dementia in long-term-care facilities.

(Footnote omitted.)

27. The above statements identified in ¶¶ 20-26 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company lacked

adequate internal controls over protocol adherence and data integrity; (2) that, as a result, the Company's principal investigator failed to adhere to the informed consent form approved by the Institutional Review Board; (3) that the Company's principal investigator failed to maintain adequate case histories for certain patients whose records were reviewed by the FDA; (4) that the Company's principal investigator fabricated email correspondence with a pharmacovigilance safety vendor that was then provided to the FDA; (5) that the foregoing would negatively impact the Company's ability to obtain regulatory approval of BXCL501 for the treatment of agitation associated with dementia in patients with probable Alzheimer's disease; and (6) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

28. On June 29, 2023, before the market opened, BioXcel filed a Current Report on Form 8-K with the SEC disclosing, in relevant part:

> In December 2022, the U.S. Food and Drug Administration ("FDA") conducted an inspection of one of the clinical trial sites in the Phase 3 TRANQUILITY II clinical trial, where the principal investigator enrolled approximately 40% of the subjects participating in the trial. At the conclusion of this inspection, the FDA issued an FDA Form 483 identifying three inspectional observations. These observations related to ***the principal investigator's failure to adhere to the informed consent form approved by the Institutional Review Board for a limited number of subjects whose records the FDA reviewed, maintain adequate case histories for certain patients whose records the FDA reviewed, and adhere to the investigational plan in certain instances***. ***For example, the FDA cited the principal investigator's delay in informing the sponsor's medical monitor or pharmacovigilance safety vendor of a serious adverse event ("SAE") for one of the subjects, which report was made to the Company's vendor outside of the 24 hour time period prescribed by the clinical trial protocol***. The principal investigator for this clinical site responded to the FDA observations within the time period requested. The FDA inspection remains open, however, as the FDA has not issued an Establishment Inspection Report.
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> In May 2023, it came to the Company's attention that ***this same principal investigator in the TRANQUILITY II clinical trial may have fabricated email correspondence purporting to demonstrate that the investigator timely submitted***

> ***to the Company's pharmacovigilance safety vendor a report of an SAE from a different subject than the one cited in the FDA Form 483, and purporting to show that the vendor had confirmed receipt***. Upon receipt of this information, the Company promptly initiated an investigation and recently received confirmation that the principal investigator fabricated the email correspondence related to the timing of the reporting of this SAE to the Company's pharmacovigilance vendor to make it appear as though this SAE had been timely reported to the pharmacovigilance vendor as required by the clinical trial protocol. The Company also confirmed that this SAE had been timely entered into the electronic data capture system, even though the SAE had not been separately reported to the Company's pharmacovigilance safety vendor within the 24 hour timeframe required under the protocol.
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> In connection with this ongoing investigation, the Company was made aware that ***the fabricated email correspondence was provided to the FDA by the principal investigator's employer during the on-site inspection in December 2022***. After unblinding of the data, the Company determined that the SAE that was the subject of this fabricated correspondence between the principal investigator and the Company's pharmacovigilance vendor occurred in a subject in the placebo arm. This principal investigator has not participated in any other clinical trial sponsored or conducted by the Company. Moreover, the study was designed such that trained study staff other than principal investigators were to conduct assessments of the primary efficacy measure.
>
> ***The Company is currently in the process of conducting an investigation into protocol adherence and data integrity at the principal investigator's trial site*** and is in the process of retaining an independent third party to audit the data collected at the site. The Company's ongoing investigation and/or the planned independent audit may uncover new findings regarding the integrity of the trial data from this principal investigator's site, the accuracy of safety or efficacy findings, or the usability of the data in connection with a marketing application. The Company plans to complete its investigation as soon as possible, although the Company can provide no assurance regarding the timing of the completion of its own investigation or the timing of the completion of the planned independent audit of the trial site. Further, ***the Company has notified the FDA of these findings*** and the steps it intends to take to validate the integrity of the data generated by this investigator for the TRANQUILITY II trial.

(Emphasis added.)

29. The Company also disclosed that "[i]n connection with the foregoing, the Company is providing the below supplemental risk factor" which states:

> ***Developments relating to the Company's TRANQUILITY II Phase 3 trial may impact the timing of the Company's development plans for, and prospects for***

> ***regulatory approval of, BXCL501 for the acute treatment of agitation associated with dementia in patients with probable Alzheimer's disease.***
>
> The timing of the Company's marketing application and prospects for regulatory approval of BXCL501 for the acute treatment of agitation associated with dementia in patients with probable Alzheimer's disease may be adversely impacted by these developments. For example, even if the Company's investigation and the independent audit conclude that data from the TRANQUILITY II trial have not been affected or compromised by the principal investigator's actions or other deficiencies at the trial site, the FDA may not accept or agree with the Company's conclusions or analyses, or may interpret or weigh their importance differently. Further, if the Company or the FDA determines that there are issues with data integrity and/or compliance with good clinical practice requirements at the trial site, the Company may be unable to use some or all of the subject data generated at this clinical site to support a marketing application. If all or a substantial portion of such data were discarded, the TRANQUILITY II trial may no longer be adequately powered for statistical significance and the Company may need to conduct a new clinical trial. If the Company conducts a new Phase 3 trial, such trial may have different safety or efficacy results from the topline data the Company is announcing today. Topline data from the TRANQUILITY II trial, including results from subjects at this principal investigator's site, may not be predictive of the results in any new trial. Further, any investigation, disqualification or debarment of, or proceeding or action against the principal investigator, or any investigation, proceeding or action against the Company, could further delay development and approval of BXCL501 for this indication, and otherwise have a material adverse effect on the Company, its financial condition, results of operations and prospects.

(Emphasis in original.)

30. On this news, BioXcel's stock price fell $11.28 per share, or 63.8%, to close at $6.39 per share on June 29, 2023, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired BioXcel securities between December 15, 2021 and June 28, 2023, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate

families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, BioXcel's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of BioXcel shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by BioXcel or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

33. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

34. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of BioXcel; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

37. The market for BioXcel's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, BioXcel's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired BioXcel's securities relying upon the integrity of the market price of the Company's securities and market information relating to BioXcel, and have been damaged thereby.

38. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of BioXcel's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about BioXcel's business, operations, and prospects as alleged herein.

39. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about BioXcel's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

40. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

41. During the Class Period, Plaintiff and the Class purchased BioXcel's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

42. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced

in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding BioXcel, their control over, and/or receipt and/or modification of BioXcel's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning BioXcel, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

43. The market for BioXcel's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, BioXcel's securities traded at artificially inflated prices during the Class Period. On February 8, 2023, the Company's share price closed at a Class Period high of $33.24 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of BioXcel's securities and market information relating to BioXcel, and have been damaged thereby.

44. During the Class Period, the artificial inflation of BioXcel's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about BioXcel's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of BioXcel and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted

in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

45. At all relevant times, the market for BioXcel's securities was an efficient market for the following reasons, among others:

(a) BioXcel shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, BioXcel filed periodic public reports with the SEC and/or the NASDAQ;

(c) BioXcel regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) BioXcel was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

46. As a result of the foregoing, the market for BioXcel's securities promptly digested current information regarding BioXcel from all publicly available sources and reflected such information in BioXcel's share price. Under these circumstances, all purchasers of BioXcel's securities during the Class Period suffered similar injury through their purchase of BioXcel's securities at artificially inflated prices and a presumption of reliance applies.

47. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972),

because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

48. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of BioXcel who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

49. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

50. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase BioXcel's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

51. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for BioXcel's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

52. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about BioXcel's financial well-being and prospects, as specified herein.

53. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course

of conduct as alleged herein in an effort to assure investors of BioXcel's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about BioXcel and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

54. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

55. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and

for the purpose and effect of concealing BioXcel's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

56. As a result of the dissemination of materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of BioXcel's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired BioXcel's securities during the Class Period at artificially high prices and were damaged thereby.

57. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that BioXcel was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their BioXcel securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

58. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

59. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

60. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

61. Individual Defendants acted as controlling persons of BioXcel within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

62. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the

particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

63. As set forth above, BioXcel and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the proposed Class, prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of herself and the proposed Class, hereby demands a trial by jury on all issues so triable.