UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TONYA HILLS and OKLAHOMA LAW ENFORCEMENT RETIREMENT SYSTEM, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. BIOXCEL THERAPEUTICS, INC., VIMAL MEHTA, RICHARD STEINHART, and ROBERT RISINGER, Defendants.	Civil Action No.: 3:23-cv-915 The Honorable Sarala V. Nagala The Honorable Robert A. Richardson CLASS ACTION

AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

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Lead Plaintiffs Tonya Hills ("Hills") and the Oklahoma Law Enforcement Retirement System ("OLERS"), individually and on behalf of all others similarly situated, by and through their undersigned attorneys, allege the following upon personal knowledge as to Lead Plaintiffs and Lead Plaintiffs' own acts, and information and belief as to all other matters. Lead Plaintiffs' information and belief is based upon, *inter alia*, Lead Counsels' investigation, which included review and analysis of: (a) regulatory filings made by BioXcel Therapeutics, Inc. ("BioXcel," "BTAI", or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) press releases, presentations and media reports issued and disseminated by the Company; (c) analyst and media reports concerning BioXcel; (d) other public information regarding the Company; and (e) investigative interviews with former BioXcel employees having first-hand knowledge of the Company's business operations. This action asserts claims arising under the United States securities laws on behalf of all investors who purchased the common stock of BioXcel during the Class Period of December 7, 2022 through August 11, 2023, both dates inclusive.

Lead Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. BioXcel is a biotechnology company that focuses on finding new therapeutic uses for pre-existing chemicals that it identifies through the use of artificial intelligence ("AI"). Its entire repertoire includes just four chemical compounds: BXCL501 and BXCL502, which are used to treat agitation in various patient populations, and BXCL701 and BXCL702, which are potential oncology therapies. BioXcel's research and development plans for BXCL501 are far more advanced than for BXCL502, BXCL701 and BXCL702.

2. Prior to the Class Period, BioXcel had secured FDA approval to use BXCL501 to treat agitation in patients with schizophrenia and bipolar disorders. It marketed BXCL501 as "IGALMI" to these patient populations. It derived scant revenue from this product in these patient populations, however, as the medical community was slow to accept BXCL501 as a treatment for these patients. But BioXcel pinned its hopes on the commercialization of BXCL501, and so it turned its attention to securing FDA approval for a new indication of BXCL501: as a treatment for agitation in patients with dementia and Alzheimer's Disease. Investors were enthusiastic, therefore, when BioXcel announced in December 2021 that it was embarking on Phase 3 clinical trials – called TRANQUILITY II and TRANQUILITY III – as the next steps in securing FDA approval for BXCL501 to treat agitation in these new patient populations.

3. In a December 15, 2021 press release to announce the new clinical trials, BioXcel's Chief Executive Officer ("CEO"), Vimal Mehta ("Mehta"), explained that there are more than 4 million Alzheimer's patients who experience agitation, showcasing the great potential for commercial success that BioXcel would achieve once BXCL501 could be prescribed for Alzheimer's and dementia patients. Analysts' reactions were predictably optimistic, with one analyst, HC Wainwright, raising its 12-month target for the price of BioXcel's common stock – which was trading at the time at $22.30 per share – to $140 per share.

4. Despite these grand aspirations, BioXcel was struggling financially. Although BioXcel was able to sell IGALMI to schizophrenia and bipolar disorder patients, the adoption of IGALMI in these patient populations was slow to gain traction. BioXcel's revenues were negligible in relation to its enormous funding requirements. Former BioXcel employees noted the Company was burning through cash and were skeptical that the Company would be able to survive, much less thrive. To stay afloat, BioXcel secured financing from two private financial backers:

Oaktree Capital Management, L.P. ("Oaktree") and Qatar Investment Authority ("QIA"). These entities loaned BioXcel hundreds of millions of dollars to carry out its clinical trials, but the release of tranches of cash was contingent on BioXcel passing hurdles along the regulatory approval pathway for BXCL501, as well as surpassing revenue thresholds. Thus, BioXcel's existence depended in large part on the success of the TRANQUILITY clinical trials. These were more than important to the Company; they were life-sustaining.

5. BioXcel appeared to be proceeding apace with its project to be able to market BXCL501 in the dementia and Alzheimer's patient populations. Throughout the Class Period, it reiterated to investors that its TRANQUILITY II trial was "progressing well" and "on track." Per Defendants' statements, investors eagerly awaited the release of the study's topline data which was promised during the second quarter of 2023. Robert Risinger ("Risinger"), the Company's Chief Medical Officer ("CMO") and the "Study Chair" of the TRANQUILITY II Study, according to the FDA, stated on May 9, 2023: "We have very high confidence in demonstrating not only efficacy but also the safety in patients living in an assisted living or residential care setting."

6. Behind the scenes, however, a different story had emerged. Under enormous pressure to deliver prompt results from the TRANQUILITY studies to BioXcel's private lenders as well as the investing community, the Individual Defendants took shortcuts. Rather than engage a reputable company to conduct these important clinical trials, BioXcel outsourced the TRANQUILITY trials to Segal Trials, a regional operation in South Florida. The principal investigator assigned to oversee the trials – Dr. Caitlin Meyer – was inexperienced, having never run a clinical trial before. Yet she was directly responsible for signing up and monitoring a clinical trial site that enrolled 40% of the TRANQUILITY II trial patients. As set forth below, employees at BioXcel were surprised and concerned that a person with relatively little experience was leading

such an important clinical trial for the Company. In addition, they perceived Segal Trials as second-rate, and believed that this company was selected because it enabled BioXcel to cut costs and hasten the regulatory approval process. Insiders confirm that Defendants Mehta and Risinger were both heavily involved in the decision to select Segal Trials.

7. This decision proved costly. The FDA conducted a site inspection of Dr. Meyer's facility and the TRANQUILITY II study from December 5, 2022 to December 21, 2022. In circumstances like this, when a new drug application is not pending or close to submission, an FDA site-visit is typically triggered by an unusual event, such as concerns about data integrity raised by a whistleblower. Following such inspections, and in only rare instances, the FDA will issue a Form 483 Letter which details serious areas of concern that must be remedied.

8. On December 21, 2022, Dr. Meyer received a Form 483 notification from the FDA (the "Form 483 Letter") outlining several observations of flaws in the TRANQUILITY II clinical trial:

- 25 of 37 patients did not have sufficient documentation showing they met all inclusion criteria. Three of these patients' files demonstrated they potentially ***met exclusion criteria of having memory impairment or cognitive impairment unrelated to Alzheimer's Disease.***
- The clinical trial was ***not being conducted in accordance with the approved protocol*** in certain instances.
- At least ***one Serious Adverse Event occurred that was not timely reported*** to the medical monitor or safety team.
- Certain study participants ***did not sign a proper consent form*** which meant they might have to be excluded from the study, resulting in insufficient participation.

9. Despite that Defendants knew about the FDA investigation and Form 483 Letter since December 2022, they did not disclose it until June 29, 2023, first in a press release and Form 8-K, and also in an analyst call. Shockingly, Defendants admitted that they had known about the

FDA investigation and Form 483 Letter. The Mizuho analyst on the call (who identified himself as "Richard on for Graig Suvannevejh" from Mizuho) asked, "[j]ust a few questions for me is that in the 8-K, you mentioned finding this out in December and then again in May, how come the company didn't disclose this sooner? What's the strategy there? Defendant Risinger responded: "***The FDA did the audit back in December. We were aware of it, and we have been monitoring that site even more closely***."

10. Despite knowing since December 2022 that the TRANQUILITY II study was jeopardized, Defendants sat on this information until June 29, 2023, when they were also able to release TRANQUILITY II's topline data. Apparently, Defendants hoped that investors' enthusiasm regarding promising topline data results would overshadow their disappointment at the lack of integrity in how the clinical trial was actually conducted. In addition to disclosing the Form 483 Letter, Defendants also disclosed that they discovered that Dr. Meyer had fabricated correspondence to the FDA in order to feign compliance with required protocols.

11. Investors were not fooled, and they realized that the TRANQUILITY II study results were questionable given the problems associated with how the trial had been conducted, including inclusion of patients who might not have met the study's participation criteria.

12. The price of BioXcel's stock plummeted 63.8% on this news, falling from $17.67 at the close of trading on June 28, 2023, to $11.28 per share at the close of trading on June 29, 2023. Analysts were dismayed. For example, an analyst report issued by Canaccord Genuity on June 29, 2023 noted that "any enthusiasm around the data was overwhelmed by the revelation in an 8-K filing that a principal investigator's (PI) actions at a site that enrolled 40% of study participants had led to an unresolved FDA Form 483, and a more recent incident that BTAI reported to the FDA." On that same day, Guggenheim issued an analyst report that stated, "[t]he

positive study news will be overshadowed by the disclosure that a single PI who enrolled 40% of the patients in the study triggered the FDA to issue a Form 483." The report went on to state that "Tranquility II data are clean, even if a bit underwhelming … but trial conduct and data integrity are a key focus."

13. There is no justification for Defendants to have waited until June 29, 2023 to disclose the Form 483 Letter other than they hoped the topline data results would counterbalance investors' negative reaction. They knew about the FDA investigation and resulting Form 483 Letter since the investigation began on December 5, 2022. Defendant Risinger admitted in the June 29, 2023 analyst call that: "***The FDA did the audit back in December. We were aware of it, and we've been monitoring that site even more closely.***"

14. Moreover, as the sponsor, BioXcel bore the ultimate responsibility for the proper administration of TRANQUILITY studies pursuant to FDA regulations. Thus, BioXcel was required to ensure that these studies were conducted in accordance with all FDA regulations and that the studies' protocols were being followed faithfully. Sponsor entities conduct regular audits to oversee the general progression and proper administration of FDA studies. BioXcel was not permitted to rely on Segal Trials or Dr. Meyer for the integrity of the clinical trials; it had to assume an active monitoring role. Further, as the problems were identified, Dr. Meyer was required under FDA guidelines to notify BioXcel, and BioXcel was required to have an active role in remedying those issues. Indeed, Defendant Risinger was the Study Chair of the TRANQUILITY II study, according to the FDA.

15. Thus, Defendants knew since at least December 2022 that the TRANQUILITY II study – into which the Company, its investors and its lenders had placed considerable hope – was seriously flawed, and further, that these flaws would have devastating consequences on the

Company and its ability to timely complete its TRANQUILITY clinical trial program which, in turn, would significantly delay any and all plans for the commercialization of BXCL501. Even if the studies were completed within the contemplated timeframe, the integrity of the data would be called into question.

16. Meanwhile, Defendants were sure to exit the scene before the damage had been done. Specifically, Defendant Mehta realized profits of $3,750,379 based on his insider sales of BioXcel common stock during the Class Period. Defendant Richard Steinhart ("Steinhart"), BioXcel's Chief Financial Officer ("CFO"), realized profits of $176,502 during the Class Period. And another insider, director and co-founder of BioXcel, Krishnan Nandabalan ("Nandabalan"), realized profits of $3,186,272 during the Class Period.

17. The announcement on June 29, 2023 was not the end of BioXcel's misery. The other shoe dropped when, before the market opened on August 14, 2023, the Company announced that management had "substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months." Defendant Steinhart stated that "the Company's previously disclosed cash runway projection assumed a full utilization of its strategic financing agreements of $155 million with Oaktree and QIA. Based on recent events, the Company is not likely to be in a position to meet the milestones to access the additional capital under the financing agreements." Further, BioXcel had paused the TRANQUILITY III clinical trial as the Company sought to meet with the FDA and re-group with its plans for filing an application for a new indication of BXCL501. Defendant Mehta stated it had planned to meet with the FDA to discuss the "entire TRANQUILITY program," including the TRANQUILITY II clinical study and resulting "data audit." This was shocking to the market, which had been assured throughout the Class Period that BioXcel had enough funding to continue for at least twelve months.

18. Investors' remaining hopes evaporated, and the price of the Company's stock declined further, from $7.40 per share at the close of market on August 11, 2023 to $4.33 per share at the close of market on August 14, 2023.

II. JURISDICTION AND VENUE

19. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)).

20. Pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, this Court has jurisdiction over the subject matter of this action.

21. Pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), venue is proper in the Judicial District. Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

22. 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.

III. PARTIES

A. LEAD PLAINTIFFS

23. Lead Plaintiff Hills is an experienced individual investor. Hills resides in Tampa, Florida, and possesses a bachelor's and master's degree in psychology from Auburn University, as well as a Juris Doctor from Stetson Law School. She has a personal real estate portfolio and also serves as President of Spencer Farms, Inc., which is a land development company. As set forth in the certification previously filed with the Court (ECF No. 30), Hills purchased shares of BioXcel common stock at artificially inflated prices during the Class Period and suffered damages

as a result of Defendants' violations of the federal securities laws and false and/or misleading statements and/or material omissions alleged herein.

24. Lead Plaintiff OLERS is a defined benefit pension fund headquartered in Oklahoma City, Oklahoma, that administers retirement benefits on behalf of members of the law enforcement profession of the state of Oklahoma and their families. OLERS manages approximately $1.07 billion in assets. As set forth in the certification previously filed with the Court (ECF No. 29), OLERS purchased shares of BioXcel common stock at artificially inflated prices during the Class Period and suffered damages as a result of Defendants' violations of the federal securities laws and false and/or misleading statements and/or material omissions alleged herein.

B. DEFENDANTS

25. Defendant BioXcel was incorporated under the laws of Delaware on March 29, 2017 and its headquarters are located in New Haven, Connecticut. BioXcel was spun off from BioXcel Corporation, which was formed in 2006. BioXcel's common stock was first publicly traded in 2018, and it trades under the symbol "BTAI" on the NASDAQ exchange. The Company raised approximately $60 million in its IPO. In addition, the Company has secured an additional $500 million in funding through private sources.

26. Defendant Vimal Mehta has served as BioXcel's CEO since May of 2017. Mehta co-founded BioXcel Corporation, and has served as its Chairman of the Board since 2005 and its CEO since September 2014. As of September 30, 2023, Defendant Mehta, through his ownership of BioXcel LLC, beneficially owns approximately 31.5% of the Company. Some of Mehta's other positions include Senior Vice President of Business Development at Inpharmatic Ltd. and Jubilant Life Sciences and Business Development Management at CuraGen Corporation. Mehta has a Ph.D. in chemistry from the University of Delhi, India and completed a Post-Doctoral Fellowship in chemistry at the University of Montpellier, France.

27. Defendant Richard Steinhart has served as the Company's Senior Vice President and CFO since October of 2017. Prior to joining BioXcel, Steinhart served as Vice President and CFO at Remedy Pharmaceutics and Senior Vice President of Finance and CFO of Mela Sciences. Steinhart has also served as an independent consultant to biotechnology and medical device companies. Steinhart is a member of the Board of Directors of Actinium Pharmaceuticals, Inc. and Atossa Genetics, Inc. He has B.B.A. and M.B.A. degrees from Pace University.

28. Defendant Robert Risinger has served as the CMO, Neuroscience, of BioXcel since May of 2021. Risinger has also served as the Senior Vice President of Clinical Development at BioXcel from December of 2018 to May of 2022. Prior to that, Risinger served as Vice President of Clinical Development at NeuroRx Pharmaceuticals and as the Senior Medical Director of Clinical Development at Alkermes. Additionally, he held roles at Bristol Myers Squibb, Ortho-McNeil Janssen Medical Affairs, and Johnson & Johnson. Risinger has a B.S. in Chemistry and Biology from Allegheny College and an M.D. from the University of Pittsburgh School of Medicine. The FDA lists Defendant Risinger as the "Study Chair" for the TRANQUILITY II clinical trial. According to his biography on BioXcel's website, "Dr. Rob Risinger has extensive experience leading clinical development from first in human through Phase 1-4 clinical trials to create a successful commercial product. His expertise includes designing and executing high quality translational studies within Phase 1 and 2 that provide insight and rapidly navigate development to successful registration trials."

C. CONFIDENTIAL WITNESSES

1. CW1

29. CW1 worked at BioXcel from November 2020 to October 2023. From November 2020 to October 2022, CW1 was an Executive Director and Head of Medical Science Liaisons at

BioXcel Therapeutics. CW1 then became a Medical Strategy/Medical Director at BioXcel and served in this position from August 2022 to October 2023.

30. CW1 stated that the clinical trial was being carried out at an investigation site in Florida. CW1 further stated that the principal investigator – Dr. Caitlin Meyer – had never previously been in charge of a clinical trial. While she was an associate investigator for other principal investigators, she had never run a trial before. CW1 stated that it seemed strange, "that we would put our most important study in the history of the company with a novice, and that 40% of patients would be there." According to CW1, "there were time pressures, so it was allowed to go. The clinical team was under strict orders that the initial high-level results needed to be in by the end of June, because there were milestones to show investors that the study was wrapped up – that a filing package to the FDA could be prepared with the goal of getting it in to the FDA by the end of 2023 – which meant the data analysis needed to start by July." CW1 stated that, "it was apparent that artificial pressures from senior management put a lot of stress on the clinical team, to find sites and get people enrolled, to meet these deadlines."

31. CW1 stated that there were weekly leadership team meetings at BioXcel, which included Kostic, Head of Medical Communications Alix Bennett, Head of the Medical Science Liaison ("MSL") team Colin Watson, Head of the Managed Care Field Team Sonja Hockett, and Biostatistician Heather Robinson ("Robinson"). CW1 reported that Robinson's role was technically in medical affairs, but she performed statistical work for clinical teams and would give others updates about how things were going. According to CW1, Robinson would periodically comment that the TRANQUILITY II trial site at Segal Trials was, "trying to get paperwork cleaned up. We're working with them."

32. According to CW1, one of BioXcel's two primary investors "had, for the end of 2023, significant milestones that needed to be met, both for commercial sales and clinical studies." CW1 was told that, "if not completed, either new funding wouldn't be available or, potentially, the company would have to kick back some money." CW1 reported that pressure related to the investor had been "bandied about for most of the whole year, especially because sales numbers were so low." These numbers were discussed on the weekly brand update calls, which were attended by the CEO. CW1 asserted that "it was already kind of known that there was no way [we] were going to be able to meet that important metric, in terms of gross sales volume." According to CW1, that is why there was pressure to get the study done and submit to the FDA.

2. CW2

33. CW2 served as a Senior Director of the MSL team at BioXcel from January 2021 to September 2022. CW2 described their function as an MSL as, "pre-approval, we talk to thought leaders or people who are experts in the area of the drug we're getting ready to launch."

34. CW2 retired from BioXcel in September 2022 but was familiar with the TRANQUILITY studies. According to CW2, Defendant Risinger was the person assigned to work with the monitor of the clinical trial site.

35. CW2 stated that the TRANQUILITY studies had been carried out by Segal Trials, which is a company that conducts clinical trials throughout its six research facilities in South Florida. According to CW2, Segal Trials was not a "legit" clinical research operator. CW2 believed the Company "screwed up" by engaging Segal Trials to conduct the TRANQUILITY II study. Specifically, CW2 stated that BioXcel carried out the study, "in a Segal Trials place, instead of a legit place, where patients already were." The C-suite level executives "thought it was going to be faster, doing it at Segal." When CW2 learned that BioXcel had decided to use Segal Trials,

CW2 recalls calling either Defendant Risinger or one of his direct reports and saying, "What happened? I thought we were going with this super legit facility."

36. CW2 reported that prior to the study's launch, the MSL team was looking for a top in-house key opinion leader ("KOL"). A key opinion leader (KOL) is a trusted, well-respected influencer with proven experience and expertise in a particular field. In healthcare, these thought leaders could be physicians, hospital executives, health system directors, researchers, patient advocacy group members, and more. KOLs in the pharmaceutical industry often consult with clinical trial sponsors in order to help inform clinical trial design. CW2 and their team recommended an Alzheimer KOL, Marc Agronin, from Miami Jewish Hospital. CW2 thought Agronin was perfect because his office was outside a residential facility with a lot of Alzheimer patients. That way, they'd "have a KOL and patients, all in one place." CW2 and her team introduced him to Cedric Burg, BioXcel's former Head of Clinical Operations. According to CW2, "next thing you know, we're ghosted and Cedric's leaving."

37. Having worked in the pharmaceutical industry for 23 years, CW2 has some personal knowledge of the process that triggered issuance of the Form 483 Letter. According to CW2, FDA visits are triggered by red flags, such as "super-fast enrollment or a lack of reporting … or if they're not getting Adverse Event reports." CW2 stated that the FDA usually does not get involved in monitoring clinical trials until companies are close to filings, and therefore something must have triggered the audit that resulted in the Form 483 Letter. CW2 noted that BioXcel would have been in regular communication with the FDA, even before the study began. Meetings between BioXcel and the FDA would have been attended by "[Research and Development ("R&D")] senior leadership, like the CEO and COO, and maybe somebody in commercial would sit in." CW2 stated that "anyone in R&D, under Risinger … legal, of course … and also the

regulatory team" would have received the Form 483 letter. Defendant Risinger confirmed that the Company knew about the FDA investigation and Form 483 Letter during the June 29, 2023 analyst call.

38. When it came to financing, CW2's perception was that Defendants, "were always trying to meet with money people. Always, always, always. Always trying to get more money. I had never seen that before. My personal opinion is they were always trying to get money and always bragging about how much money they got, and then they'd pay themselves." CW2 continued that, "[a]ll [Mehta] was interested in was money, money, money, money … It was widely discussed, with some teams."

3. CW3

39. CW3 was a Senior Director at BioXcel for two years from 2020 through 2022. CW3 oversaw the drug supply and reported to David Hanley, former senior vice president of global pharmaceutical development and operations, who in turn reported to Defendant Mehta.

40. CW 3 was aware of compliance issues at the TRANQUILITY II clinical trial site. CW3 stated, "I'm not surprised it happened, because they went with somebody who gave them the best deal." According to CW3, it was internally known that the principal investigator at the site, i.e., Dr. Caitlin Meyer, "was somebody known to the CEO and others, and they could get a lot of data from them for minimal investment." CW3 had learned this information from an officer of the Company, whom CW3 said is still employed at the Company. CW3 stated that it was common knowledge that the CEO knew the principal investigator.

41. According to CW3, in hiring this principal investigator for the "good deal," "it felt like they were cutting corners. They didn't check much on the reputation of the investigator, and so on." CW3 reported that there was "a lot of skepticism" from a specific BioXcel officer about

this principal investigator, i.e., Dr. Meyer. Moreover, concerns about Dr. Meyer were widely held, "with people familiar with the study."

42. CW3 reported he has heard trepidation "a couple times, from a couple different people … just, regarding the study." According to CW3, "there was a lot riding on the study" and one of the concerns surrounding the study was whether the trial was being conducted properly.

4. CW4

43. CW4 was a former Associate Director of Financial Planning & Analysis ("FP&A") and Head of FP&A at BioXcel from January 2022 through February 2023. CW4 reported "directly to the CFO, with a dotted line to Vice President of Finance, Scott Szilagvi." His day-to-day activities included "regular FP&A reporting, system implements, getting reports composed to budget."

44. According to CW4, the Company was "burning cash." CW4 spoke frequently with his colleagues about the rate the Company was spending cash. CW4 explained that he prepared financials in Excel, and the file was provided to the Vice President of Finance, Scott Szilagyi ("Szilagyi") and the CFO, Defendant Steinhart. CW4 stated, "I used to provide a worksheet of different scenarios, like, if we would get additional funding from Oaktree – or different scenarios. I was just concerned with how much money we spent, compared with what we were getting." These were done at least once a month. If Szilagvi or Steinhart needed something more urgent, CW4 would do an update.

45. CW4 continued: "We were constantly analyzing how much we would get from Oaktree. We wanted to see how long we would last, if we didn't get funded." CW4 would provide Steinhart and Szilagvi with monthly reports on performance and "on an ad hoc basis." According to CW4, Steinhart "wanted to know how long we'd last, with or without investment." CW4 prepared spending reports at least twice a month.

5. CW5

46. CW5 was an Executive Director at BioXcel from July of 2020 to April of 2022. CW5 oversaw research programming and worked one level below the Vice President. According to CW5, the job was as a "medical monitor on some developmental studies." CW5 "would look at safety data and make look good things that we were writing, for the purposes of conducting studies." CW5 reported directly to Defendant Risinger. CW5 reported that Risinger, "was kind of monolithic" and that "he just ran everything." CW5 also said that Risinger made "all the development decisions … on a microscopic level." According to CW5, Risinger attended meetings with other C-suite level executives "every day."

6. CW6

47. CW6 was an Institutional Sales Specialist at BioXcel from November of 2022 to June of 2023.

48. CW6 was part of the sales team that was attempting to sell BXCL501 for its FDA-approved use in patients with schizophrenia and biopolar disorders. CW6 reported that, "as sales people, we were really just trying to get this drug off the ground. But we really didn't have any traction. People weren't interested. We were presenting in ER settings. But there you need immediate sedation – and IGALMI doesn't work for like 30 minutes."

49. CW6 reported skepticism about BioXcel's ability to financially sustain itself. CW6 stated, "[f]rom the beginning, [BioXcel] said they had enough [funding] to sustain until 2023," but CW6 did not believe that. In reference to drug sales, CW6 stated, "they sold a couple boxes here, a couple boxes there." CW6 went on to state, "I was making $165,000 a year. I think most people were making $160,000 a year. I didn't know how they were going to do it. I just kept scratching my head, and immediately started looking elsewhere, because I thought, 'This isn't going to come to fruition.'"

7. CW7

50. CW7 was the Head of CMC Regulatory Affairs from July of 2020 to March of 2022. CMC stands for "chemistry, manufacturing and control." CW7's job entailed making sure that BioXcel manufactures a drug supply "on a timely basis, and that how" it is manufacturing the drug supply adheres to the NDA (New Drug Application).

51. According to CW7, Defendant Mehta was "involved" in choosing sites and vendors for clinical operations. CW7 described Defendant Mehta as "a hands-on CEO. In meetings he always came across as a very hands-on CEO." CW7 stated that company executives "were involved in site selection," and that "compared with other CEOs" CW7 worked with, Defendant Mehta's involvement in clinical site selection was "more than expected. He was involved." CW7's impression of Defendant Mehta's involvement comes from the fact that they attended several meetings together, and even if he was not present at a meeting, often the other attendees were told, "This is a request from Vimal [Mehta]," and "We have to run it by Vimal [Mehta]." According to CW7, Defendant Mehta was "more hands-on than other CEO's" that CW7 has worked for. According to CW7, "[e]ven the smallest amount of contracts had to be signed off by Vimal [Mehta] or Richard [Steinhart]. I'm not used to that. Usually there's a cap for every position, but not with them. Usually you say, 'This position can approve up to $50,000. This position can approve up to $100,000. But at BioXcel, pretty much every contract had to be signed by Richard [Steinhart] and sometimes by Vimal [Mehta]."

52. CW7 described weekly team meetings. There were weekly minutes issued after every meeting. The meeting was attended by clinical operations, medical affairs, and Chetan Lathia and Rob Risinger. Vice presidents, senior directors and executive directors attended as well. Defendant Mehta was "in and out" but received minutes of these meetings.

53. CW7 reported that, "[t]here was a great deal of interest to start the dementia study. They wanted to get it done quickly. To get the data. That's as far as I heard at meetings. The CEO and the whole board was very active and involved in meetings." CW7 further stated that Defendant Mehta was "interested in this study because it was important to us; important to the company's survival." CW7 explained that there was "always" a discussion about getting clinical trials done quickly. "They wanted to get the work done fast." Further, CW7 stated that "the timeline that [former head of clinical operations] Cedric Burg came up with they pretty much found unacceptable. They wanted it to be done faster, and they found a CRO who would do it with the timeline the CEO expected it to be."

54. CW7 also reported about that Chetan Lathia, who is a Senior Vice President and head of translational medicine, pharmacology and regulatory affairs at BioXcel, and was also "head of preclinical" research. Lathia "had a responsibility" and "made sure the CEO was aware of any changes, or if he thought something couldn't be done or would need a longer timeline, or if a regulatory strategy was devised or changed during a meeting," Lathia "would make sure [Mehta] was aware."

55. CW7 also reported that in March of 2022, "a lot of people" left BioXcel, including Cedric Burg. CW7 stated that, "at small companies, you really have to have a lot of trust in the management, which I didn't, per se."

56. In regard to BioXcel's finances, CW7 reported that there were "rumors going around" and that "there were people that were not happy with how finances were being handled."

IV. FACTS

A. BACKGROUND OF BIOXCEL

57. BioXcel is a clinical stage biopharmaceutical company. BioXcel was spun off from BioXcel LLC, which was formed in 2006. The Company was incorporated in Delaware on March

29, 2017. BioXcel's stock was first publicly traded in March of 2018. As of December 31, 2022, it employed approximately 185 full-time employees (including approximately 70 sales representatives). In addition to funding raised in the IPO, Defendant Mehta had raised approximately $500 million in capital to support the Company's R&D and commercial efforts.

58. According to the Company's 10-K for the fiscal year ended December 31, 2022, BioXcel "leverages existing approved drugs and/or clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications."

59. BioXcel boasts that it was using a novel strategy which employed artificial intelligence in the drug development process. Specifically, the Company examines drugs that are, or have previously been in, Phase II or Phase III clinical trials and uses AI to find new uses for them. Defendant Mehta consistently lauded this unique process and attempted to differentiate BioXcel from its competitors.

60. BioXcel's entire product line derived from just four chemical compounds. BXCL501 and 502 were chemical compounds used to treat agitation, and BioXcel was looking for new indications for these in various patient populations. BXCL701 and 702 were potential oncology and leukemia therapies. Of these four, BXCL501 was far ahead of the other three in terms of advancing through the clinical trial process and proceeding towards commercialization.

B. BIOXCEL DEVELOPED BXCL501 TO TREAT AGITATION

61. BioXcel's sole commercially viable product, IGALMI, resulted from use of AI in the drug development process. Specifically, by using AI, BioXcel was able to identify a new application for dexmedetomidine ("dex"), branded as Precedex, which was originally used as a sedative. BioXcel's newly discovered application for dex is labeled as BXCL501 and is for the acute treatment of agitation associated with neuropsychiatric disorders, such as schizophrenia and

bipolar disorder. BXCL501 is an investigational, proprietary, orally dissolving, sublingual thin film formulation of dexmedetomidine, administered under the supervision of a health care provider, that is placed under the tongue or behind the lower lip. The FDA approved BXCL501, branded as IGALMI, for the treatment of agitation in schizophrenia and bipolar patients in April of 2022.

62. BioXcel touted BXCL501 as one of its two most advanced clinical development programs at the Company. During the 4Q21 earnings call, on March 10, 2022, Defendant Mehta emphasized to investors that BXCL501, one of BioXcel's "lead product candidates" had "shown promising results through clinical development, including publication in prestigious journals, such as JAMA and JITC and we couldn't be more excited for the future of our neuro … franchise[]." Later during that same call, Defendant Mehta stated, "[a]nd as -- just to remind everyone, when we became a public company in March of 2018, we had selected these 2 assets, BXCL501 and 701. [BXCL501] is very close to approval… So we are super excited for both the assets we have in our portfolio."

63. IGALMI, however, was experiencing minimal commercial success. The first IGALMI sales team was deployed in May 2022. In its Form 10-K for 2022, BioXcel announced that it had "expanded its institutional sales force to 70 representatives in December 2022" with the goal of "driv[ing] awareness" of IGALMI. Despite these efforts, the Company recognized only $375,000 in revenues in FY 2022, $206,000 in revenues in the first quarter of 2023, and $457,000 in revenues in the second quarter of 2023.

64. Notably, CW6, an Institutional Sales Specialist at BioXcel, reported that IGALMI was difficult to sell. CW6 thus expressed skepticism about BioXcel's ability to financially sustain itself. CW6 stated that "[f]rom the beginning, [BioXcel] said they had enough to sustain until

2023." In reference to IGALMI drug sales, CW6 stated, "they sold a couple boxes here, a couple boxes there." CW6 went on to state, "I was making $165,000 a year. I think most people were making $160,000 a year. I didn't know how they were going to do it. I just kept scratching my head, and immediately started looking elsewhere, because I thought, 'This isn't going to come to fruition.'"

C. BIOXCEL ANNOUNCES CLINICAL TRIAL STUDIES TO GAIN FDA APPROVAL OF BXCL501 FOR THE TREATMENT OF DEMENTIA RELATED AGITATION

65. On December 15, 2021, BioXcel first announced that it had begun to evaluate BXCL501 for the treatment of acute agitation associated with Alzheimer's disease in a press release titled, "BioXcel Therapeutics Initiates Pivotal Phase 3 Program of BXCL501 for Acute Treatment of Agitation in Patients with Alzheimer's Disease."

66. According to this press release, 12 million Americans over the age of 65 are expected to be impacted by Alzheimer's Disease by 2040, and up to 70% of Alzheimer's patients experience agitation, "with an estimated 100 million agitation episodes occurring in the United States every year."

67. The press release further explained that BioXcel's clinical studies would consist of "two randomized, placebo-controlled, adaptive, parallel group pivotal trials" titled TRANQUILITY II and TRANQUILITY III. Defendant Mehta stated:

> 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. This marks an important advancement in potentially bringing this novel treatment to the more than 4 million patients, who experience agitation as one of [Alzheimer's Disease'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.

68. The press release described elements of the TRANQUILITY trials in detail, including how agitation would be measured in patients. Each TRANQUILITY trial would include

150 dementia patients that are 65 years or older. TRANQUILITY II enrolled patients in assisted living or residential facilities who required minimal assistance with daily life activities. TRANQUILITY III enrolled patients in nursing homes with moderate to severe dementia who required greater assistance with daily life activities.

69. According to the FDA, the trial would take place over 12 weeks. Subjects in the trial were required to reside in a care facility where study-related procedures and drug dosing would be performed. The subjects would receive a maximum of 28 doses throughout the trial. Once a subject has been administered all 28 doses of BXCL501, they would be monitored for the remainder of the 12-week study period. Subjects would receive a single film of BXCL501 40 µg dose or BXCL501 60 µg dose or placebo in a 1:1:1 randomization scheme.

70. The trial had specific inclusion and exclusion criteria for its subjects. Some of the requirements for inclusion are that a subject had to: (1) have a diagnosis of probable Alzheimer's Disease; (2) have episodes of psychomotor agitation; (3) exhibit behaviors that congruent with the International Psychogeriatric Association criterion for agitation; (4) provide informed consent; and (5) be deemed to be medically appropriate for study participation by the principal investigator.

71. Moreover, the following criteria would necessitate a subject's exclusion from the trial: (1) subjects with dementia or other memory impairment not due to probable Alzheimer's Disease; (2) clinical diagnosis of probable Alzheimer's Disease should not be applied when there is evidence of a cerebrovascular incident temporally related to the worsening of cognitive function; (3) subjects with agitation caused by acute intoxication; (4) subjects with significant risk of suicide or homicide per the investigator's assessment; (5) subjects who are medically unstable or in recovery; (6) history of clinically significant syncope or syncopal attacks, orthostatic hypotension within the past 2 years, current evidence of hypovolemia, orthostatic hypotension, bradycardia; (7)

subjects who had a total score of >13 (i.e., high fall risk) on the John Hopkins Fall Risk Assessment Tool; (8) subjects with laboratory or ECG abnormalities; (9) subjects who have received an investigational drug within 30 days prior to Screening; and (10) subjects who are currently suffering from substance abuse. Patients with a potential cause for delirium (relatively recent onset agitation and dementia).

D. BIOXCEL'S FINANCING DEPENDED ON PASSING REGULATORY HURDLES FOR BXCL501'S PROPOSED NEW INDICATION

72. BioXcel's IGALMI was the only product that the FDA had approved, but it yielded little revenue, as the patients it was indicated for – schizophrenia and Bipolar disorders – were slow to adopt it. With little to no revenue coming in from the sales of IGALMI, there was virtually nothing to sustain the Company's operations.

73. The dismal revenues from IGALMI created significant pressure for BioXcel to secure its new indication for BXCL501. Not only did it need to boost its revenue stream, but it was forced to rely on private loans to fund its commercial and developmental efforts, and disbursement of these funds, in turn, depended on BioXcel clearing regulatory hurdles for BXCL501's use in Alzheimer's and dementia patients.

74. On April 19, 2022, the Company issued a press release which disclosed that it had entered into a "$260 million strategic financing with Oaktree and Qatar Investment Authority." In the same press release, BioXcel highlighted that this "extends [the] Company's cash runway into 2025."

75. In its Form 10-K filed with the SEC on March 16, 2023, the Company further stated:

> In April 2022, we entered into financing agreements with affiliates of Oaktree Capital Management, L.P. and Qatar Investment Authority that provides for up to $260 million in gross funding to support the Company's commercial activities of IGALMI sublingual film and the expansion of clinical development efforts of

> BXCL501, which includes a Phase 3 program for the acute treatment of agitation in patients with Alzheimer's disease, and for general corporate purposes.
>
> On April 19, 2022 (the "Effective Date"), the Company entered into two strategic financing agreements: (i) a Credit Agreement and Guaranty (the "Credit Agreement") by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto (the "Lenders"), and Oaktree Fund Administration LLC ("OFA") as administrative agent, and (ii) a Revenue Interest Financing Agreement (the "RIFA"; and together with the Credit Agreement, the "OFA Facilities") by and among the Company, the purchasers party thereto (the "Purchasers") and OFA as administrative agent. Under the OFA Facilities, the Lenders and the Purchasers agreed to, in the aggregate between the two OFA Facilities, provide up to $260,000 in gross funding to support the Company's commercial activities of IGALMI sublingual film. In addition, the OFA Facilities are intended to support the expansion of clinical development efforts of BXCL501, which includes a Phase 3 program for the acute treatment of agitation in patients with Alzheimer's disease, and for general corporate purposes. The Lenders and Purchasers are comprised of affiliates of Oaktree Capital Management, L.P. and Qatar Investment Authority.

76. This strategic financing agreement consisted of the following: (1) a Credit and Guaranty Agreement in the amount of up to $135 million, (2) a Revenue Interest Financing Agreement in the amount of up to $120 million, and (3) rights to purchase shares of the Company's stock in the amount of approximately $5 million.

77. In its Form 8-K filed with the SEC on April 19, 2022, the Company disclosed certain aspects of the Credit and Guaranty Agreement. Particularly, BioXcel was loaned $135 million in senior secured term loans to be released in tranches, bearing an annual interest rate of 10.25% payable quarterly.

78. The first tranche consisted of $70 million, and was accessible within 30 calendar days after the Company's receipt of approval from the FDA of an NDA with respect to BioXcel's BXCL501 product for the acute treatment of agitation associated with schizophrenia or bipolar I or bipolar II disorder. This was accomplished with the FDA's approval of IGALMI, which was

received on April 5, 2022. The $70 million in funding was thereafter released to the Company on April 28, 2022.

79. BioXcel could access the remaining two tranches under the Credit and Guaranty Agreement prior to December 31, 2024, in such amounts and subject to the following restrictions: "$35 million upon satisfaction of certain conditions, including receipt of certain regulatory and financial milestones; and $30 million upon satisfaction of certain conditions, including specified minimum net sales of the Company attributable to sales of BXCL501 for a trailing twelve consecutive month period."

80. In the same Form 8-K, the Company also disclosed certain aspects of the Revenue Interest Financing Agreement. Pursuant to this, BioXcel was to be provided access to $120 million, again to be released in tranches, for the near-term commercial activities of IGALMI, the development and commercialization of BXCL501, and other general corporate purposes. In lieu of interest payments, the Company will pay royalties ranging from 7.75% to 0.375% on net sales of BXCL501 in the U.S., subject to a cap of 175%.

81. The first tranche consisted of $30 million, and was available upon FDA's approval of IGALMI. The funds were released to the Company on July 8, 2022.

82. The remaining two tranches under the Revenue Interest Financing Agreement may be drawn by the Company prior to December 31, 2024, in equal distributions of $45 million, upon satisfaction of certain conditions, including receipt of certain regulatory and patent related milestones and specified minimum net sales of BXCL501 during any consecutive twelve-month period.

83. During the 1Q22 earnings call on May 9, 2022, Defendant Mehta stated that BioXcel, "announced a $260 million strategic financing with Oaktree Capital and Qatar

Investment Authority." Mehta went on to state that, "[f]ull execution with financing will extend our cash runway into 2025…" A longer cash runway meant that BioXcel had more opportunity to pursue the development and commercialization of new drugs. As such, analysts paid attention to the cash runway projections from BioXcel. For example, in an analyst report dated May 11, 2022, UBS wrote that BioXcel's "recently announced $260mn in financing (Oaktree/Qia) provides a meaningful cash runway" and that it would take the company through new drug development which was "the sentient element of [UBS's] buy thesis."

84. But the strategic financing agreements dictated that BioXcel was only eligible to receive additional funding tranches once it satisfied certain conditions, including receipt of certain regulatory milestones associated with the TRANQUILITY II and TRANQUILITY III trials, and reaching specified minimum net sales attributable to sales of BXCL501–for a trailing twelve consecutive month period. Thus, BioXcel's success depended in large part on its ability to secure FDA approval for BXCL501's new indication.

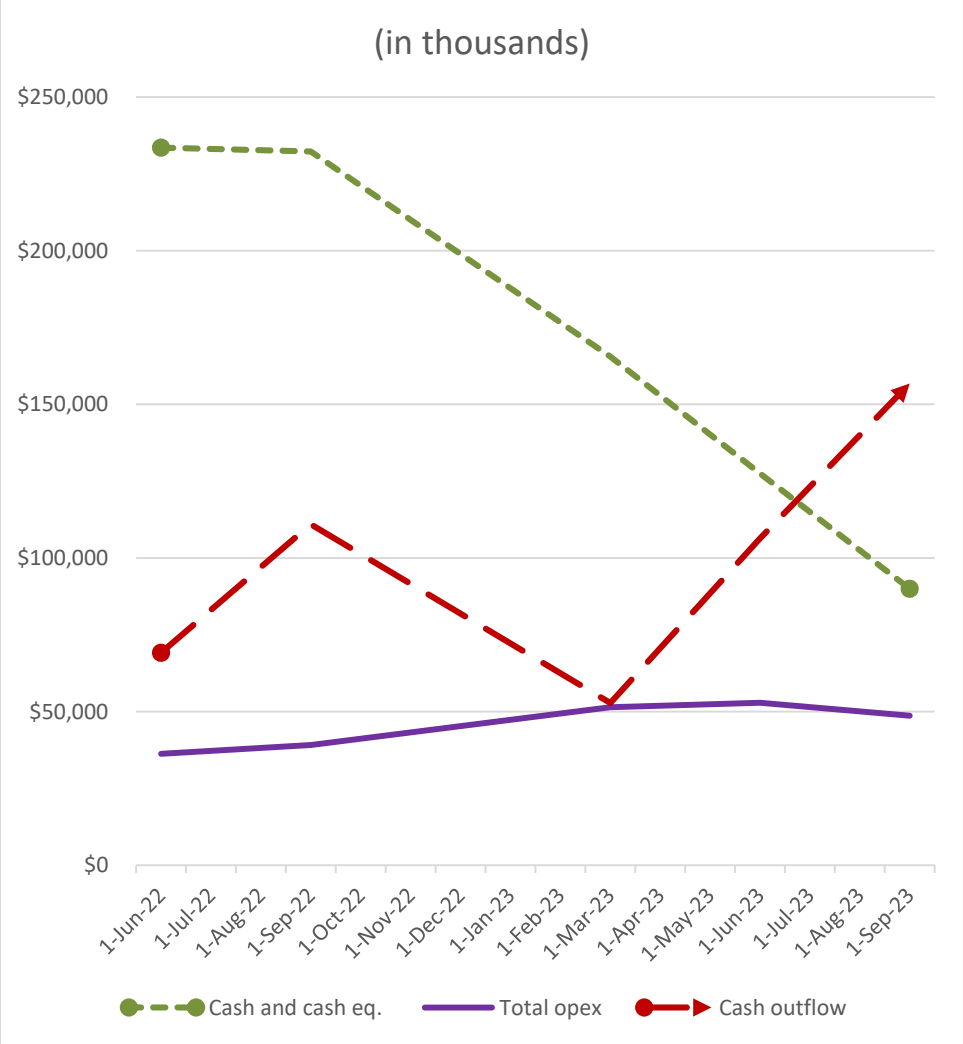
85. CW1, who was an Executive Director and Head of Medical Science Liaisons at BioXcel until October 2023, stated that "there were milestones to show investors" that studies associated with the commercialization of BXCL501 for Alzheimer's and dementia patients were "wrapped up" by the end of 2023. Thus, the Company needed "high-level results" from the TRANQUILITY trials by the end of June. CW1 reiterated that BioXcel's two primary investors "had, for the end of 2023, significant milestones that needed to be met, both for commercial sales and clinical studies."

86. CW4, who was the head of BioXcel's FP&A group from January 2022 through February 2023, described the dire financial condition of the Company, stating it was "burning

cash" and "constantly analyzing how much" additional funding it could get from private investors such as "Oaktree." It "wanted to see how long [it] would last if [it] didn't get funded."

E. UNDER FINANCIAL PRESSURE, BIOXCEL RUSHES THE TRANQUILITY CLINICAL TRIALS

87. An analysis of the Company's publicly-reported financial information reveals that the Company was indeed "burning through cash," as CW 4 stated. A summary of as the Company's quarterly short-term assets (in the form of cash and cash equivalents), total operating expenses, and cash flows is shown below:



88. Not only was the Company not profitable even after IGALMI's approval, but in fact it began hemorrhaging cash as it ramped up its sales efforts and embarked on the TRANQUILITY studies. In its Form 10-Q filed with the SEC on May 9, 2023, the cash flow statement shows that the funds from the first tranche of the strategic financing agreement had been fully accounted for, as of March 31, 2023, and cash flow from financing was now being sourced from equity. Nevertheless, the Company recorded a net decrease of cash and cash equivalents in the amount of $28,204,000.

89. In its cash flow statement contained in the Form 10-Q filed with the SEC on August 14, 2023, the Company recorded a net decrease in cash and cash equivalents of $66,180,000. This meant that as of June 30, 2023, BioXcel had already used up almost all of the initially released funds from the strategic financing agreement.

90. BioXcel's dire financial condition and need to deliver data by specific deadlines from its TRANQUILITY trials to Oaktree and QIA caused Defendants to make costly mistakes. Principally, BioXcel engaged Segal Trials, a second-rate clinical trial company because it believed that this company would enable it to speed up the TRANQUILITY II and III trials. Segal Trials is a privately held network of six research sites in Florida conducting Phase1-IV research trials.

91. The principal investigator at the Segal Trials site in North Miami, where the TRANQUILITY II trials occurred, was an inexperienced investigator, Dr. Caitlin Meyer. In fact, she had never before overseen a clinical trial. Despite this, she was charged with enrolling and overseeing a whopping 40% of the patients enrolled in the critical TRANQUILITY II study.

92. Former employees were shocked to learn that BioXcel entrusted the TRANQUILITY II trial to Segal Trials and Dr. Meyer. For example, CW2, characterized Segal Trials as not a "legit" clinical research operator, but noted that the Company "thought it was going

to be faster, doing it at Segal." CW2 stated that the Company "screwed up" when it engaged Segal Trials.

93. CW1 stated that Dr. Meyer had never before been in charge of a clinical trial. CW1 remarked that it seemed strange for BioXcel to place such an important project in the hands of an inexperienced investigator, but noted that there were "strict orders that the initial high-level results" were "in by the end of June, because there were milestones to show investors that the study was wrapped up." CW1 was told that "if not completed, either new funding wouldn't be available or, potentially, the company would have to kick back some money."

94. Dr. Meyer's inexperience is evident through her unprofessional conduct in handling the reporting of adverse events. When on June 29, 2023 the Company disclosed the problems in the TRANQUILITY II Study, it also stated that Dr. Meyer had fabricated an email during the FDA's onsite inspection in December 2022 to make it appear that she had reported adverse events in a timely manner, when in fact she had not. Specifically, the Company reported that Dr. Meyer "fabricated email correspondence purporting to demonstrate that the investigator timely submitted to the Company's pharmacovigilance safety vendor a report of an SAE . . . to make it appear as though this SAE had been timely reported to the pharmacovigilance vendor as required by the clinical trial protocol."

95. The Company's former employees confirmed that the Company's dire financial situation and need to satisfy its lenders explained Defendants' choice of Segal Trials and Dr. Meyer to conduct TRANQUILITY II. As reported by CW1, CW2, and CW4, Defendants placed an exceptional amount of significance on receiving financing. According to CW1, Defendants created pressure to get the TRANQUILITY trials done quickly in order to meet regulatory milestones that would ensure the receipt of funding. CW1 stated that, in 2023, pressure related to

these financers had been "bandied about for most of the whole year" and these numbers were consistently discussed in weekly brand update calls, where Defendant Mehta was present. CW2 reported that Defendants were abnormally concerned with money. According to CW2, Defendants were always trying to meet with money people and get more money. Moreover, as reported by CW4, Defendants were constantly analyzing how much they could get from Oaktree and how long BioXcel could last if it did not get the funding.

96. Defendants were also under pressure to keep their promises to the larger investing community. They were acutely aware that analysts and investors were eagerly waiting positive news from the TRANQUILITY trials. Their exuberance fueled lofty stock valuations throughout most of the Class Period, when it traded above $30 per share for significant stretches.

97. Analyst reports reflected this enthusiasm. For example, on December 5, 2022, an analyst report issued by Canaccord Genuity stated that, "[w]e await key data from the TRANQUILITY II Phase 3 for Igalmi in the acute treatment of agitation in Alzheimer's disease (AD) in 1H23. This indication, for which there are no currently approved products, presents a significantly larger market opportunity than Igalmi's approved indication." Likewise, on March 14, 2022, an analyst report issued by Berenberg Capital Markets stated that "[w]ith such broad application potential, BXCL501 could have blockbuster opportunity if it proved efficacy and received approval in all of the indications." And on May 10, 2022, an analyst report issued by Berenberg Capital Markets stated that "[o]btaining expanded labeling for BXCL501 as a potential treatment for three other neuropsychiatric disorders including agitation in dementia … could expand the market opportunity significantly."

98. On May 11, 2023, HC Wainwright issued an analyst report that noted BioXcel's revenue miss but states, "[d]espite the lackluster recent revenue data, we believe that investor focus

remains on near-tear clinical data releases for BXCL501 (the original code designation for IGALMI), which could support label extensions into multiple additional niches that may drive considerable revenue accretion." On June 1, 2023, an analyst reported issued by Canaccord Genuity noted that, "[a] positive outcome on TRANQUILITY II would bolster investor confidence and be good for the company AND that stock."

99. In fact, the development of BXCL501 for the treatment of dementia related agitation was so important to investors that it overshadowed the news of IGALMI being approved for the treatment of agitation associated with schizophrenia or bipolar I or II disorder on April 6, 2022. For example, on April 6, 2022, an analyst report issued by UBS stated that, "[w]hile the approval of Igalmi is a big moment for the company and an incremental positive for the Buy thesis, the key to upside and central tenet of our Buy thesis is the opportunity in Alzheimer's dementia (data in '23)." The report went on to label "Phase 3 TRANQUILITY II data" as a key upcoming event. Also on April 6, 2022, an analyst report issued by Guggenheim acknowledge the approval of IGALMI but then went on to state that: "We also note that approval in other indications (e.g., Alzheimer's agitation) could facilitate an out-patient dosing, which could be a big deal for the drug as it would represent a much larger market opportunity and a bit different reimbursement dynamics."

F. THE FDA'S CLINICAL TRIAL COMPLIANCE REQUIREMENTS

100. As part of the FDA approval process, the FDA monitors clinical trials to ensure compliance with regulatory requirements, which in turn, ensure accurate safety and efficacy data.

101. The FDA's bioresearch monitoring protects the rights of a human research subject and the accuracy of the data produced by the study. As explained in more detail below, if a clinical trial site fails to adhere to regulatory requirements, the FDA may issue a Form 483 which details observations of deficient and improper conduct during the clinical trial. Although, throughout the

development process of a drug, the drug's sponsor has the responsibility to ensure its that the clinical trials comply with regulatory requirements which will avoid the issuance of a Form 483.

1. Bioresearch Monitoring

102. Bioresearch monitoring (previously defined as "BIMO") is the FDA's compliance program that monitors clinical trials. The BIMO program serves to protect the rights, safety, and welfare of human research subjects in clinical trials; verify the accuracy, reliability and integrity of clinical trial data submitted to the FDA; and evaluate compliance with the FDA's regulations governing conduct in clinical trials, including regulations for information consent and ethical review.

103. Through the BIMO program, the FDA conducts inspections of clinical trials in order to determine the credibility and accuracy of clinical data that will be submitted to the FDA. When an NDA is not pending, the FDA only conducts onsite inspections if there is a reason to do so, such as for example, if concerns about data integrity or patient enrollment are brought to its attention. Generally, these inspections may involve interviews with the principal investigator of a clinical trial site as well as review of the principal investigator's processes, records, data and documentation. The standards against which these inspections are conducted are FDA regulations in Title 21 of the Code of Federal Regulations Parts 11, 312, 50, 54, and 56 (21 CFR §§ 11, 312, 50, 54, 56) and Good Clinical Practice ("GCP").

2. A Form 483 and Its Consequences

104. After the FDA conducts an inspection of a clinical trial site, in rare instances, it will decide to issue a written Form 483. The FDA issues a Form 483 when an FDA inspector has observed any conditions that may constitute violations of the FD&C Act, other Acts, or other FDA regulations. Typically, an FDA investigator will discuss their observations during the inspection with the principal investigator. After the inspection ends, the FDA investigator will present the

Form 483 and discuss the observations with the principal investigator of the clinical trial site. However, it is in fact very rare for a clinical investigator to receive a Form 483 at the conclusion of an inspection and only occurs in response to significant violations.

105. According to the FDA, a Form 483 is issued when, "in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."

106. If a clinical investigator receives a Form 483, the FDA requires that corrective actions addressing each inspectional observation occur.

107. In response to the inspection findings that resulted in a Form 483, the FDA may pursue advisory, administrative or judicial actions. Some consequences of regulatory violations include clinical holds, which immediately suspends or imposes restrictions on an ongoing or proposed clinical study; Warning Letters issued by the FDA; disqualification of a principal investigator from participating in clinical studies.

3. A Sponsor's Responsibility

108. According to the FDA, a sponsor is a person that takes responsibility for and initiates a clinical investigation. This person can be either an individual or pharmaceutical company. BioXcel was the sponsor for the TRANQUILITY clinical trials. Defendant Risinger was the designated "Study Chair," according to the FDA.

109. 21 CFR § 312.50 states that "[s]ponsors are responsible for . . . ensuring proper monitoring of the investigation[s], ensuring that the investigation[s] is conducted in accordance with the general investigational plan and protocols contained in the [Investigational New Drug Application]."

110. Sponsors are responsible under FDA regulations for all of the clinical trial's operational aspects. This involves ensuring that the clinical trials be conducted properly for submission to the FDA and that the subjects' rights and welfare be protected.

111. Sponsors are required to monitor clinical trial sites and principal investigators through audits to ensure investigational activities are being carried out as planned, and in accordance with FDA regulations and GCP. BioXcel itself had a duty and an obligation to monitor the trial site and conduct its own audits to satisfy itself that the trial was being conducted in accordance with its approved protocols and all regulations. This oversight is crucial in ensuring the adequate protection of the rights, safety, and welfare of the participants in the clinical investigation and the integrity of the data submitted to the FDA.

112. Typically, when a study sponsor engages a principal investigator, there is a contract in place that states that the study sponsor must be notified directly and promptly when a Form 483 Letter is issued. This contract is described in 21 CFR § 312.52: "A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. ***Any such transfer shall be described in writing***." The FDA regulations also impose this notification obligation.

113. Once a Form 483 letter is issued, the sponsor of the study is required to participate in any corrective actions alongside the principal investigator.

G. BioXcel Receives and Conceals a Form 483 Letter Issued by the FDA for Compliance Violations at Its Primary Research Site

114. While Defendants touted the safety and efficacy results from TRANQUILITY II, and the progress towards meetings its projected timeline for the release of topline data, the reality was that one of the study's main clinical trial sites faced serious compliance issues. Defendants

knew this, and continued to mislead investors about the TRANQUILITY II study throughout the Class Period.

115. From December 5, 2022 through December 21, 2022, the FDA conducted an inspection of the North Miami trial site, and concluded that it was noncompliant with accepted and recognized protocols in several respects, described below.

116. On December 21, 2022, the FDA issued a Form 483 Letter to BioXcel. The FDA issues a Form 483 Letter when an investigator from the FDA observes any conditions that constitute a violation of the FD&C and related Acts.

117. The Form 483 Letter noted several violations that had occurred within the TRANQUILITY II clinical trial at the North Miami trial site.

118. First, the investigator found that Meyer failed to prepare or maintain adequate case histories. Specifically, "25 out of 37 subjects reviewed and were randomized into the study and received investigational product did not have sufficient documentation to show they met all inclusion/exclusion criteria." This is an extremely serious violation. Without sufficient documentation, there is no way to verify that the study participants were in fact the proper subjects of the study. Inclusion of participants that were not the proper subjects of the study undermines all the results of the study. Further, the potential that certain subjects would have to be excluded for insufficient documentation or inability to meet inclusion criteria could further jeopardize the study's ability to achieve enough numbers to give meaning to the results.

119. Second, the principal investigator at this site issued summaries of consent forms to patients who were not approved by the FDA's Institutional Review Board ("IRB"). The Form 483 stated that, "[f]our out of 37 subjects reviewed were initially consented using a Spanish short form that was not approved by the IRB. Furthermore, the short form used did not contain information

describing the basic elements of informed consent to include risks and study procedures." Thus, the clinical trial had signed up patients who had not provided consent under the FDA's regulations. This violation was extremely serious. Patients who did not provide proper consent could be excluded from study results, which could mean the study did not have sufficient participants to draw any meaningful conclusions from the study.

120. Third, the FDA investigator found that the TRANQUILITY II trial included patients who ***should have been excluded from the trial*** based on their medical histories. It stated, "Three of these subjects' files contained documentation they potentially met exclusion criteria of having memory impairment or worsening of cognitive function unrelated to probable Alzheimer's Disease." As above, this violation was extremely serious. Inclusion of patients whose cognitive disfunction was unrelated to Alzheimer's Disease is pointless in a study that is designed to measure whether BXCL501 could treat Alzheimer's patients.

121. Fourth, the FDA investigator found that in conducting the trial, Meyer did not follow the protocols set out in the signed statement of investigator and investigational plan. Specifically, four of the subjects, "were initially dosed with investigational product using a urinary drug screen (UDS) … prior to dosing contrary to the protocol established schedule of events used to demonstrate subjects did not meet exclusion criteria."

122. Moreover, Meyer was not reporting Serious Adverse Events ("SAE") within the 24-hour time period required by the protocol. An SAE is defined as an untoward medical occurrence in a subject that is fatal, life-threatening, or can result in hospitalization. The FDA found that Meyer had failed to adhere to the timeframe on one occasion. But this was not the only time Meyer failed to adhere to such timeframe. In fact, the Company reported that in May 2023, it had discovered that Meyer had fabricated an email correspondence in order to make it appear as

though she had timely reported another SAE. This SAE was separate from the one cited in the FDA Form 483.

V. THE TRUTH IS REVEALED

123. Defendants spent months misleading the public as to the legitimacy and progress of the TRANQUILITY II trials and, in turn, BioXcel's ability to access capital under its financing agreements with Oaktree and QIA. However, the truth was finally revealed in a series of corrective disclosures. First, on June 29, 2023, Defendants disclosed the issuance of the Form 483 by the FDA and the numerous compliance violations that occurred at the TRANQUILITY II clinical trial site. Second, on August 14, 2023, Defendants disclosed that BioXcel had limited liquidity and had doubts about its ability to continue as a going concern.

A. JUNE 29, 2023

124. Before the market opened on June 29, 2023, 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.
>
> 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.
>
> 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.)

125. The company went on to disclose that "[i]n connection with the foregoing, the Company is providing the below supplemental risk factor." This risk factor 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.)

126. In an analyst call on June 29, 2023, an analyst from Mizuho asked, on behalf of Graig Suvannavejh, "[j]ust a few questions for me is that in the 8-K, you mentioned finding this out in December and then again in May, how come the company didn't disclose this sooner? What's the strategy there?" Defendant Risinger responded, "***The FDA did the audit back in December. We were aware of it, and we've been monitoring that site even more closely***."

127. 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.

128. In reaction, analysts all but ignored the release of TRANQUILITY II's topline data and focused instead on the negative news concerning the integrity of the TRANQUILITY II study.

For example, an analyst report issued by Canaccord on June 29, 2023 noted that while BioXcel also disclosed topline data from the TRANQUILITY II clinical trial, "any enthusiasm around the data was overwhelmed by the revelation in an 8-K filing that a principal investigator's (PI) actions at a site that enrolled 40% of study participants had led to an unresolved FDA Form 483, and a more recent incident that BTAI reported to the FDA." On that same day, Guggenheim issued an analyst report that stated, "[t]he positive study news will be overshadowed by the disclosure that a single PI who enrolled 40% of the patients in the study triggered the FDA to issue a Form 483." The report later stated that "Tranquility II data are clean, even if a bit underwhelming … but trial conduct and data integrity are a key focus."

129. Indeed, analysts recognized right away that problems of this magnitude jeopardized the positive topline data results from TRANQUILITY II that the Company was reporting, and in fact could lead to significant delays, or even the Company's absolute disability, in getting FDA approval for BXCL501 for Alzheimer's and dementia patients.

130. During the analyst call on June 29, 2023 that accompanied the announcement, the very first analyst to speak, Colin Nigel Bristow from UBS Investment Bank, stated, "Congrats on the data. You certainly kept us all waiting . . . I just wanted to touch on the 493. Can you talk about what gives you comfort that the findings won't impact your ability to seek approval on this data set? And then can you talk about if there's any other sites [sic] being inspected and why the inspection of the sort of [named] site is still showing up as open?"

131. The second analyst question also concerned the Form 483 Letter. Robyn Kay Shelton Karnauskas from Trust Securities, Inc., asked whether the "efficacy results hold up when you exclude" the 40% of the patients enrolled under Dr. Meyer. Ms. Karnauskas further noted that she had "not seen this in [her] career" and asked whether "there is any precedent for 483 like

this having an impact on approvability." Defendant Risinger noted that the FDA might "repeat the efficacy, let's say analysis with individual subjects that may be out of question."

132. Sumant Satchidanand Kulkarni, an analyst from Canaccord Genuity Corp., asked what was "the earliest" the Company could "announce the results of an independent audit of the data? . . . Asked another way, I guess, how confident are you in your ability to interact with the FDA in the second half on a potential path for NDA submission?"

133. Another analyst asked, "if [the FDA] were to exclude the safety portion [of the TRANQUILITY II study], what's your confidence that they won't exclude all of these patients from this one site?"

B. AUGUST 14, 2023

134. On August 14, 2023 (pre-market), BioXcel announced 2Q23 results and disclosed a restructuring to extend cash runway and the pausing of the TRANQUILITY III trial after observing agitation episodes in study participants. It also announced doubts about its ability to continue as a going concern.

135. Specifically, BioXcel disclosed the following in its 10-Q for the third quarter of 2023:

> The Company's history of significant losses, its negative cash flows from operations, potential near-term, increased covenant-driven payments under its OFA Facilities (as defined in Note 8, Debt and Credit Facilities), its limited liquidity resources currently on hand, and its dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, have resulted in management's assessment that ***there is substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months*** from the issuance date of the financial statements included in this Quarterly Report on Form 10-Q.

136. During the earnings call later that same day, Defendant Steinhart stated:

> The Company's previously disclosed cash runway projection assumed a full utilization of its strategic financing agreements of $155 million with Oaktree Fund Administration and Qatar Investment Authority. ***Based on recent events, the***

> ***Company is not likely to be in a position to meet the milestones required to access the additional capital under the financing agreements.*** The Company is exploring multiple ways to extend its cash runway and is already in discussions with its strategic financing partners to amend the agreements. Successful modification of these agreements could extend the company's cash runway.

137. Defendant Mehta also announced a "commercial reorganization" which would involve reducing the workforce from 190 to 80 employees. The remaining employees would focus on building "potential label expansions" and "support[ing] IGALMI."

138. Defendant Mehta also announced that the Company had "***requested a meeting with the FDA to discuss [its] entire TRANQUILITY program***. ***This will include both TRANQUILITY II, TRANQUILITY III clinical trials, the data audit and the data package that may be required to support submission of an sNDA*** seeking approval of 501 for the acute treatment of agitation in mild to moderate dementia patients with probable Alzheimer's disease. We hope to have an update on the TRANQUILITY program, including the audit and FDA meeting by the end of the year."

139. Finally, Defendant Mehta announced that "[r]egarding TRANQUILITY III, we paused enrollment after early trial data showed a much higher background frequency of agitation episode than originally expected."

140. Defendant Steinhart announced that the Company's expenses for the second quarter 2023 increased from $17.9 million Q2 2022 to $27 million in Q2 2023. This was attributed, among other reasons, to increased expenses associated with TRANQUILITY II.

141. The market reacted accordingly to this devastating news. BioXcel's stock price decreased from $7.40 per share on August 11, 2023 to $4.33 per share on August 14, 2023.

VI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

142. Throughout the Class Period, Defendants made false and misleading statements about BioXcel's clinical trial program and the Company's financial health. Specifically,

Defendants emphasized the progress of TRANQUILITY II, the clinical trial designed to evaluate the safety and efficacy of BXCL501. However, Defendants failed to disclose that the FDA had conducted a site inspection at the North Miami clinical trial site where approximately 40% of patients in the TRANQUILITY II study were enrolled from December 5, 2022 – December 21, 2022. By December 21, 2022, an FDA inspection resulted in the Form 483 Letter, which detailed numerous violations at this site. Defendants knew that these violations and the Form 483 Letter would most likely impact regulatory approval of their drug. By May of 2023, after conducting their own investigation, Defendants had also discovered that the same principal investigator had fabricated an email given to the FDA in an attempt to demonstrate that Meyer complied with the reporting requirements for SAEs, when in fact, she had not. Defendants knew of each of these adverse facts but rather than disclosing any of them, they continued to assure investors that TRANQUILITY II was on track.

143. Moreover, Defendants' lies about the legitimacy of the TRANQUILITY II data helped conceal the reality that BioXcel faced dire liquidity problems. Without a successful clinical trial, its main source of funding, Oaktree and QIA, would not continue to provide funds. But Defendants chose to assure investors about the Company's clinical trial program, and, in turn, its ability to access capital to fund its ongoing R&D and commercialization efforts. In truth, BioXcel was experiencing significant losses, negative cash flows from operations, potential near-term, and increased covenant-driven payments. Additionally, BioXcel's limited liquidity resources and failure to receive funding from investors to support its operations meant that BioXcel would not meet its 2025 cash runway, as promised to investors.

A. FALSE STATEMENTS ISSUED BETWEEN DECEMBER 2022 AND FEBRUARY 2023

144. On December 7, 2022, Defendants gave a presentation at the Bank of America 2022 Virtual Biotech SMID Cap Conference. During the presentation, Defendant Mehta told investors

that, "***TRANQUILITY 2 is in advanced stages of enrollment, and it's progressing well*** and we expect that data readout again in first half of 2023. So we have 2 pivotal data readouts in first half of 2023."

145. The statement identified in ¶ 144 is false. The TRANQUILITY II study was not "progressing well." To the contrary, on December 5, 2022, the FDA initiated a BIMO investigation into the North Miami clinical trial site, which comprised 40% of the TRANQUILITY II study and was being overseen by Dr. Meyer who was an inexperienced principal investigator employed by a disreputable clinical trial company. By the date of the above statement, Dr. Meyer had already violated study protocols by, *inter alia*, failing to exclude ineligible trial participants and failing to adhere to the study's informed consent requirements. Consequently, although the study was in "advanced stages of enrollment," BioXcel faced an acute risk of adverse regulatory action that would invalidate the TRANQUILITY II data, materially delay progression of the Company's clinical trial plan, and necessitate additional capital to remediate the protocol failures and/or complete the trial.

146. On January 11, 2023, during the 41st Annual J.P. Morgan Healthcare Conference, Defendants presented a PowerPoint that stated the ***"Phase 3 TRANQUILITY II Pivotal Trial"*** was ***"on Track in 1H 2023."*** Within that same presentation, Defendants also represented that the "TRANQUILITY II Trial" had "***Progressed***" on a "***Strong Foundation***".

147. During this presentation, Defendant Mehta went on to discuss Alzheimer's-related agitation and tout the TRANQUILITY II trial. Mehta stated, "[i]n addition, almost 100 million episodes in Alzheimer's-related agitation. There is no current approved therapy. Anything that is used to manage agitation has a black box warning. Like antipsychotics, benzodiazepine, we have a completely novel mechanism. It, we believe, target the causal mechanism of agitation. ***So we***

are very excited about TRANQUILITY II data. That is expected again in first half of 2023. So we have 2 pivotal data readouts in first half of 2023."

148. The statements identified in ¶¶ 146 and 147 are false. In fact, at the time these statements were made, Defendants had received the Form 483 Letter listing several serious protocol violations requiring immediate corrective action, which demonstrated that the TRANQUILITY II study was neither "on Track in 1H 2023" nor on a "Strong Foundation." The study conducted at the North Miami clinical trial site was responsible for 40% of the overall study patients and under the care of Dr. Meyer. As the Form 483 stated, Dr. Meyer enrolled patients who should have been excluded, failed to maintain accurate patient histories, included patients who did not give proper consent in accordance with FDA mandates, and was not following proper protocols regarding administration of the drug. It was therefore also false for Defendant Mehta to state that BioXcel was "excited about the TRANQUILITY II data" because he was in possession of information concerning problems with compliance in the TRANQUILITY II study that called into question the integrity of the data and materially increased the risk of further adverse regulatory action. No reasonable person would be "excited" about the data under those circumstances.

149. On February 21, 2023, BioXcel held its first BXCL501 Key Opinion Leader Day event ("KOL event"), during which Defendant Mehta provided, in pertinent part:

> And I'm very pleased to stand here and see that we have an approved drug in our neuroscience franchise. And now we have achieved human proof of concept with our immune-oncology asset, which is BXCL701. Today, for the first time, all focus is going to be on that. I know most of the time we talk about the neuroscience business. So just to give highlight our first drug, IGALMI got approved in about 3.5 years from first in-human all the way to the NDA approval, and it has been launched within a 4-year window. ***There are multiple opportunities to expand the market potential for this product***, and we have upcoming 3 data readouts. ***One is Alzheimer's-related agitation, TRANQUILITY II;*** SERENITY III, which is for at-home use. And third is our MDD. So all 3 ***data readouts are on track, and we are excited to announce that in first half of 2023***.

150. The statements identified in ¶ 149 are false. Defendant Mehta represented that the TRANQUILITY II study was "on track" in the context of "expand[ing] the market potential" for the drug when, in reality, BioXcel had already received the Form 483 requiring immediate corrective action, such that BioXcel's clinical trial and commercialization plans would be delayed significantly. Indeed, on December 21, 2022, the risk of noncompliance and regulatory action materialized when the FDA issued a Form 483 Letter citing violations of trial protocols for patient enrollment and recordkeeping, in addition to, finding a failure to properly report adverse events. As a result, BioXcel now faced material risks that the trial data would be considered invalid or inaccurate, that the Company would incur additional costs to validate the topline results, that the expanded commercialization of BXCL501 would be delayed or abandoned, and that the Company would miss regulatory milestones required by its financing agreements with Oaktree and QIA threatening its liquidity strength, all of which individually and collectively materially contradicted Defendant Mehta's representation that BioXcel was "on track" for "expand[ing] the market potential" for BXCL501.

B. FALSE STATEMENTS MADE IN CONNECTION WITH THE COMPANY'S FISCAL YEAR 2022 FINANCIAL RESULTS

151. On March 16, 2023, BioXcel filed its Form 10-K for the period ended on December 31, 2022. Mehta and Steinhart signed the Form 10-K on behalf of BioXcel. The Form 10-K disclosed that BioXcel relied on third parties to conduct its trials while at the same time concealing that its primary investigator for 40% of the TRANQUILITY II patients had violated study protocols and that BioXcel had received the Form 483 as a result. Specifically, the 10-K stated:

> ***We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

> We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the member states of the EEA and comparable foreign regulatory authorities for all of our products in clinical development.
>
> Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. ***If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.*** We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. ***Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.***
>
> If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced ***or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.*** As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

152. These statements were misleading because Defendants presented the risk as only a hypothetical problem, but in fact, Defendants already knew that there were problems in the North Miami TRANQUILITY II trial site, and in fact, its key principal investigator had already failed to

comply with regulations, thus calling into question the "quality [and] accuracy of the clinical data" obtained there.

153. Furthermore, the statements were false because, as Defendant Mehta disclosed on August 14, 2023, the Company had requested a meeting with the FDA to discuss the "entire TRANQUILITY program," including the TRANQUILITY II clinical trial and the data audit. Thus, the risk disclosed in this statement had in fact already materialized, and had caused delays for the TRANQUILITY program.

154. In the Company's Form 10-K for the fiscal year ended December 31, 2022, issued on March 16, 2023, the Company disclosed that: "We expect that our cash and cash equivalents as of December 31, 2022 will be sufficient to fund our ongoing research and development efforts and commercialization efforts for at least twelve months from the date of the issuance of the consolidated financial statements included in this Annual Report on Form 10-K."

155. The Company's statement in ¶ 154 is false because on December 21, 2022, the FDA had already issued a Form 483 Letter for violations in the TRANQUILITY II clinical trial. This Form 483 Letter affected Defendants' ability to meet regulatory milestones required by the Company's financing agreements with Oaktree and QIA. Thus, Defendants had reason to believe that the Company knew it would not be able to extend its cash runway into 2025. Indeed, on August 14, 2023, the Company announced its cash runway had run short, and it had doubts about its ability to continue as a going concern.

156. On March 9, 2023, Defendants held an earnings conference call to discuss BioXcel's operational and financial results for the fourth quarter of 2022. During the earnings call, Defendant Mehta stated, in pertinent part:

> [T]urning to our robust clinical pipeline; ***we believe the upcoming quarter may represent a watershed moment for the company. In the second quarter, we expect***

> ***to announce pivotal clinical data that potentially supports significant market expansion opportunities for our lead neuropsychiatric program, BXCL501.*** We believe this agitation market remains under-diagnosed and underserved. It is comprised of an estimated 139 million agitation episodes per year across bipolar disorder, schizophrenia and Alzheimer's; our 3 priority indications across various medical settings.
>
> Specifically, we expect to announce data from 2 Phase III pivotal studies for 501 in the second quarter. These studies include TRANQUILITY II trial and SERENITY III trials. Our TRANQUILITY program is designed to evaluate 501 for the acute treatment of Alzheimer's-related agitation; up to 100 million agitation episodes are estimated to occur annually in this patient population in the U.S. where currently, there are no approved FDA therapies. ***The TRANQUILITY II trial is fully enrolled and then – and the data cleaning and verification process has begun.***

157. The statements identified in ¶ 156 are false because Defendant Mehta discussed positively the TRANQUILITY II trial and BioXcel's progress towards expanding the market for BXCL501 while at the same time concealing the material adverse developments that had recently occurred with respect to the FDA's issuance of the Form 483 Letter. The Form 483 Letter was significant insofar as Dr. Meyer's site comprised 40% of the TRANQUILITY II patients, meaning that a material portion of the study data was potentially invalid due to violations of trial protocols for patient enrollment and recordkeeping, in addition to, finding a failure to properly report adverse events. Thus, contrary to Defendant Mehta's statements above, BioXcel faced a material risk that the trial data would be considered invalid or inaccurate, that the Company would incur additional costs to validate the topline results, that the expanded commercialization of BXCL501 would be delayed or abandoned, and a material risk the Company would miss regulatory milestones required by its financing agreements with Oaktree and QIA threatening its liquidity strength.

158. During the 4Q22 earnings call, Defendant Steinhart discussed the Company's "cash" providing, in pertinent part, "Cash and cash equivalents totaled $193.7 million at December 31, 2022, compared to $233 million at December 31, 2021. ***The company believes that full execution of our strategic financing with Oaktree and the Qatar Investment Authority would result in a cash runway into 2025***."

159. Defendant Steinhart's statements identified in ¶ 158 are false and/or materially misleading because by this point in time "full execution of [BioXcel's] strategic financing" was no longer possible, given that the FDA had already issued the Form 483 and BioXcel was required to take immediate corrective action. The adverse regulatory action had already caused delay, and would continue to cause delay, in terms of BioXcel meeting clinical trial development milestones under its financing agreements with Oaktree and QIA. Consequently, Defendants materially misled investors by portraying "full execution" as something that was still possible and, in turn, concealing the fact that BioXcel was facing a material liquidity crisis that would result in the Company being unable to extend its cash runway into 2025. Indeed, on August 14, 2023, the Company announced its cash runway had run short, and it had doubts about its ability to continue as a going concern.

160. During the Question-and-Answer portion of the 4Q22 earnings call held on March 9, 2023, Sumant Kulkarni ("Kulkarni"), an analyst from Canaccord, asked Defendants about the TRANQUILITY II trial. Kulkarni asked "What is a typical timeline for data verification and cleaning for a relatively quick trial like this?" Defendant Risinger responded that, "So realize this is – although it's a quick trial, it's a 3 months duration for any particular patient. And so there's a range of dosing for patients, some doses or some patients may have only had a couple of doses, other have had many, and we have to do what's called source data verification. So we literally check the numbers that are entered in our database against what's in the clinical medical records. That's actually a lot of work. ***So it's anywhere from 8 to 10 weeks of literally daily work by many people to make sure our data is accurate, correct and precise***."

161. Defendant Risinger's statement that there was "literally daily work by many people to make sure our data is accurate, correct and precise," was false because in fact, the data from the

TRANQUILITY II study was not "accurate, correct and precise." Rather, the study conducted at the North Miami clinical trial site, which hosted a large portion of the TRANQUILITY II study, had enrolled patients who should have been excluded, failed to maintain accurate patient histories, included patients who did not give proper consent in accordance with FDA mandates, and was not following proper protocols regarding administration of the drug. These deficiencies called into question the integrity of the overall study and undermined the accuracy and precision of all the data it generated.

C. FALSE STATEMENTS ISSUED IN CONNECTION WITH THE COMPANY'S FINANCIAL RESULTS FOR THE FIRST QUARTER 2023

162. During the 1Q23 earnings call on May 8, 2023, Defendant Mehta stated: "On the clinical front, we are very excited for 3 key data readouts across our lead neuropsychiatric program, BXCL501. ***These data readouts are on track and expected to enable significant potential market expansion*** . . . . Up to an estimated 100 million agitation episodes occur annually in the U.S., our ***TRANQUILITY II program continues to advance, and we are on track to report top line data in June***."

163. Defendant Mehta's statements in ¶ 162 were false. Nearly five months earlier, Defendants received the Form 483 Letter which explained that, in fact, there were numerous deficiencies and violations associated with the portion of the TRANQUILITY II trial at the North Miami site. These deficiencies meant that any data which was ultimately released would be subject to scrutiny and lack of confidence in their accuracy. Further, the Form 483 had also materially and negatively impacted BioXcel's "market expansion" efforts given the delay that the Form 483 would have on the Company's clinical trial.

164. During that same call, while discussing BioXcel's first quarter 2023 financial results, Defendant Steinhart stated that:

> Net revenue was approximately $206,000 for the quarter, similar to our prior quarter. ***We expect to see a notable uptick in revenue in the second half of the year as we believe we will continue to accrue more formulary approvals***. Research and development expenses were $27.8 million for the first quarter of 2023 compared to $18.6 million for the same period in 2022. ***The increased expenses were primarily attributable to multiple clinical trials and CMC costs related to our upcoming 3 data readouts.*** Sales, general and administrative expenses were $23.6 million for the first quarter of 2023 as compared to $12.9 million for the same period in 2022. The increased expenses were primarily attributable to personnel, sales, market access and marketing costs associated with the commercialization of IGALMI in the United States. BioXcel Therapeutics had a net loss of $52.8 million for the first quarter of 2023 compared to a net loss of $31.5 million in the same period of 2022. Cash and cash equivalents totaled $165.5 million as of March 31, 2023. ***We believe that full execution of our strategic financing with Oaktree and Qatar Investment Authority and IGALMI revenues will result in a cash runway into 2025.***

165. Defendant Steinhart's statement in ¶ 164 is misleading because it failed to disclose the Form 483 and the fact that it had already delayed and would continue to delay BioXcel's clinical trial program as well as prevent BioXcel from achieving "full execution" of its required milestones under its financing agreement with Oaktree and QIA. Thus, Defendants knew that revenue in the "second half" from additional "formulary approvals" of BXCL501 would not be possible and that, given the increased costs associated with the Form 483 corrective action, BioXcel would require additional capital that it would not be able to obtain from Oaktree or QIA. As a result, Defendants had reason to believe that the Company would not be able to extend its cash runway into 2025.

166. The next day, during a presentation at the Bank of America ("BofA") Global Healthcare Conference on May 9, 2023, Gregory Allen Harrison ("Harrison"), an analyst from BofA Securities, Research Division asked: "… And then the other one that's a big focus among investors is TRANQUILITY II in Alzheimer's agitation. What should we be looking for in this update and in this setting?" Risinger answer, "***That trial is completed. The last patient has completed. The data is being locked and undergoing verification***. That trial was powered based

on TRANQUILITY I, which showed efficacy not only for the primary measure, the same primary measure for TRANQUILITY II, but it also separated statistically on each and every secondary or confirmatory measure, the modified Cohen-Mansfield index, agitation-calmness evaluation scale, and both CGI improvement and severity. ***We have very high confidence in demonstrating not only efficacy, but also the safety in patients living in an assisted living or residential care setting***."

167. Harrison followed up by asking, "Okay. And as far as efficacy, what is the bar there in your mind for a successful trial?" To which, Risinger responded:

> Well, it's, again, the FDA has given us breakthrough therapy precisely because this is an innovative approach. We're dosing patients only when they need it, when they have an acute episode of agitation. And so of course, in the elderly, safety is critical. We're demonstrating in this study whether or not it's safe. ***From what we've seen so far, we're confident that we'll be able to take this package.*** In terms of efficacy, we simply have to demonstrate what we've already demonstrated in TRANQUILITY I.

168. Defendant Risinger's statement in ¶ 167 was false. In fact, the TRANQUILITY II study was not complete. Rather, the FDA had sent the Form 483 which indicated that the study enrolled patients who had not properly consented, included patients who should have been excluded, failed to maintain accurate patient histories, and failed to administer the drug in accordance with the study's FDA-approved protocol. Moreover, the principal investigator Dr. Meyer fabricated an email to the FDA which had purported to show that the principal investigator complied with reporting requirements for SAEs. In reality, Dr. Meyer had not submitted information about a SAE to the Company's pharmacovigilance safety vendor within the timeframe required by the investigational protocols. Further, any "confidence" that Risinger or the Company had about "demonstrating" the efficacy and safety of BXCL501 for Alzheimer's and dementia patients was undermined by the factors outlined in the Form 483 Letter, which was not disclosed.

169. On May 9, 2023, BioXcel filed its Form 10-Q for the quarter ended March 31, 2023. Defendants Mehta and Steinhart signed the Form 10-Q on behalf of BioXcel. In the Form 10-Q, the Company disclosed that it "believes that its existing cash and cash equivalents will be sufficient to cover its cash flow requirements for at least the next 12 months from the issuance date of these condensed consolidated financial statements."

170. This statement was false. In fact, just three months later on August 14, 2023, the Company announced that there was substantial doubt about the Company's ability to continue as a going concern because it had "limited liquidity resources" on hand. It was further misleading because it failed to disclose that on December 21, 2022, the FDA issued a Form 483 Letter for violations in the TRANQUILITY II clinical trial. This Form 483 Letter affected Defendants' ability to meet regulatory milestones required by the Company's financing agreements with Oaktree and QIA. Thus, Defendants had reason to believe that the Company would not be able to extend its cash runway into 2025. Indeed, on August 14, 2023, the Company announced its cash runway had run short, and it had doubts about its ability to continue as a going concern.

D. FALSE AND MISLEADING STATEMENTS ISSUED BETWEEN MAY 2023 AND JUNE 2023

171. On May 25, 2023, the Company held a Special Call for investors to discuss topline results for BioXcel's SERENITY III clinical trial. During the call, Defendant Mehta provided, in pertinent part, that:

> Beyond SERENITY III, we are very excited about BXCL501's recent and upcoming data readout, which we believe showcases its pipeline within a product potential. These include the positive top line data we announced for the major depressive disorder program last week, and our TRANQUILITY II trial examining 501 in Alzheimer's-related agitation expected in June. As a reminder, our Alzheimer's-related agitation program is evaluating 40- and 60-microgram doses of BXCL501 in TRANQUILITY II and III.
>
> In elderly patient, the exposure levels of the 60-microgram dose are almost double and equivalent to the 120-microgram dose in adults. Additionally, the 60-

> microgram dose met all 5 efficacy endpoints in the TRANQUILITY I study. ***We are confident in the TRANQUILITY II design and plan.*** These catalysts support BXCL501 potential in multiple neuropsychiatric conditions of significant unmet medical need and reinforce the breadth and depth of our innovative neuroscience portfolio.

172. The statements identified in ¶ 171 are false and/or materially misleading. As evidenced by the Form 483, Dr. Meyer had violated the "TRANQUILITY II design and plan" rendering that the data from the trial was potentially invalid and inaccurate. This created a material risk that the expanded commercialization of BXCL501 would be delayed or abandoned, all of which was contrary to Defendant Mehta's representation that he was "confident" in the study's outcome.

173. During a presentation at the Jefferies Healthcare Conference on June 8, 2023, Chris Howerton from Jefferies Group LLC asked Mehta: "Okay. All right. Well, let's say, Vimal, we're going to get those stupendous data at the end of this month. Can you file an SNDA right after that? Or, I guess, what would be the regulatory expectations after that?" Defendant Mehta responded, "So that's a great question. ***It depends on the data***. How well is efficacy data as well as safety. And if you think about the need for these patients, 100 million episodes, even if it's half of the market and half of them are in nursing home or who are more frequent agitation, which we are doing capturing In TRANQUILITY II. We will have a conversation with the FDA, ask them what do we need to file the SNDA, and then fill those gaps and file it. ***If they allow us to file it with TRANQUILITY II, we'll be ready to go, basically, if we don't need to generate anything***."

174. This statement was misleading because it omitted to disclose that, in fact, that Defendants had received the FDA issued the Form 493 Letter on December 21, 2022, calling into question the integrity of the TRANQUILITY II Study. Notwithstanding, Defendant Mehta disregarded these facts in the above statement by representing that it "depend[ed] on the data" as to whether the FDA would allow BioXcel to "file [the sNDA] with TRANQUILITY II . . . if we

don't need to generate anything." Thus, the analyst was left with the impression that there were no problems with the TRANQUILITY II study, when in fact, the integrity of the data was compromised for the reasons explained in the Form 483 Letter.

175. During the Goldman Sachs Healthcare conference on June 14, 2023, Defendant Risinger told investors that BioXcel had "***a lot of confidence in being able to demonstrate both efficacy and safety***" through the TRANQUILITY II trials.

176. Defendant Risinger's statement about the data from TRANQUILITY II was misleading because it omitted to disclose that, due to the violations laid out in the Form 483 issued by the FDA, the efficacy and safety data produced from the TRANQUILITY II were compromised.

VII. SCIENTER ALLEGATIONS

177. As alleged herein, the Individual Defendants acted with scienter in that the Individual Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the company, or in their own name, were materially false or misleading; knew or recklessly disregarded 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. Defendants, by virtue of their receipt or access to information reflecting the true facts regarding the Company, their control over, or receipt, or modification of the Company's materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

178. The Individual Defendants knew or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class

Period without the knowledge and complicity, or at least the reckless disregard, of the BioXcel personnel at the highest levels of the Company.

A. THE INDIVIDUAL DEFENDANTS HAD ACTUAL KNOWLEDGE THAT THE TRANQUILITY II CLINICAL TRIALS WERE FLAWED

179. In addition to the facts set for the above, the following facts demonstrate that the Individual Defendants had actual knowledge about the FDA inspection of the TRANQUILITY II trial conducted from December 5 to December 21, 2022, and about the Form 483 Letter issued to Dr. Meyer on December 21, 2022.

1. Defendant Risinger Admitted that the Company Knew About the FDA Investigation Since December 2022

180. Scienter is established by Defendant Risinger's own ***admission that the Company knew of the FDA investigation since December 2022.*** On June 29, 2023, the analyst from Mizuho (who identified himself as "Richard on for Graig Suvannavejh") asked Defendant Risinger, "[j]ust a few questions for me is that in the 8-K, you mentioned finding this out in December and then again in May, how come the company didn't disclose this sooner? What's the strategy here?" Defendant Risinger responded, "***The FDA did the audit back in December. We were aware of it, and we've been monitoring that site even more closely***." Notably, Defendant Risinger ignored the part of the question about ***why*** there was a delay, and simply confirmed that the Company did indeed know about the FDA investigation since December 2022.

2. The Form 483 Letter

181. As previously explained, the FDA investigated the North Miami clinical trial site for the TRANQUILITY II study which resulted in issuance of the Form 483 Letter. The investigation occurred prior to the filing of an NDA. An investigation like this can occur prior to the filing of an NDA if it is triggered by complaints concerning the trial's data integrity. As such, this inspection would have been considered a "for cause" inspection.

182. Furthermore, Dr. Meyer was required to report the inspection and the receipt of the Form 483 Letter to BioXcel. She was obligated both by FDA regulations and by any contract she most likely had in place with the Company. Thus, it is impossible that BioXcel would not have known about the Form 483 Letter.

183. A sponsor is required to conduct audits of its clinical trial sites and investigators to ensure that the clinical investigator and all research team members assisting in the conduct of a clinical trial are informed about their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, FDA guidance, and institutional policies. By law, BioXcel either knew prior to or upon receipt of the Form 483 that: (1) the short-informed consent form in Spanish that had been provided to research subjects, was not approved by the IRB, and did not include risks to subjects and study procedures (which would have been flagged by the IRB as missing); (2) the subjects who were enrolled in the study and received investigational product potentially met exclusion criteria; (3) certain aspects of the study were not being conducted according to the approved protocol; and (4) the SAE that was not reported within the timeframe required by the protocol.

184. Even without conducting its own audit, BioXcel knew about these compliance violations after the FDA conducted an inspection of the North Miami Site and subsequently issued the Form 483. Dr. Meyer was required to notify BioXcel of the inspector's arrival and inspection. Upon this notification, BioXcel was required to have staff on site, at least, during the close out meeting, where the FDA investigator discusses the content of the Form 483.

185. After the issuance of the Form 483, BioXcel and Dr. Meyer were expected to cooperate fully with the FDA to determine the cause and scope of these deficiencies and to assess their effect on the safety, effectiveness, or quality of the data submitted to the FDA and the effect

on the rights, safety, and welfare of patients in the study. Typically, an internal review is conducted and involves an outside independent consultant(s) who is qualified by training and experience to conduct such a review. The corrective plan should be committed to in writing and submitted to the FDA. Any reports generated through this plan should also be submitted to the FDA for their review.

186. In addition, participating in the corrective actions of the Form 483 Letter was in the best interests of BioXcel. The failure to correct the problems could result in having to re-do significant portions of the TRANQUILITY II study or the complete halting of the study. Given how important TRANQUILITY II was to BioXcel, it is inconceivable that the Company did not participate in developing and overseeing the corrective actions.

187. Indeed, the Company admitted that it knew of the severe consequences associated with failure to abide by FDA regulations or the study protocol. In its SEC filings, it stated that "we could encounter delays if a clinical trial is suspended or terminated by . . . the FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in imposition of a clinical hold . . ."

188. The Company further acknowledges in its public filings that "delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues."

3. The Success and Funding of the Company Depended on Approval for BXCL501 for Alzheimer's and Dementia Patients

189. BioXcel's continued existence was heavily dependent on its ability to gain FDA approval to proscribe BXCL501 to Alzheimer's and dementia patients. BioXcel had only one

other commercially viable product, which was IGALMI, and which yielded disappointing revenues. The only other asset with any commercial potential it even owned – the chemical called BXCL701 – was far behind BXCL501 in clinical trials and commercial development.

190. In addition, BioXcel was depending on loans from Oaktree and QIA that were conditioned on its ability to get FDA approval for BXCL501 for Alzheimer's and dementia patients. Without such funding, BioXcel faced difficulty in continuing as a going concern, as it revealed on August 14, 2023.

191. The Company admitted that its success was heavily dependent on achieving approval for proscribing BXCL501 for Alzheimer's and dementia patients. It stated in its public filings, "In the near term, we are dependent on the success of IGALMI and four of our product candidates, BXCL501, BXCL502, BXCL701 and BXCL702. If we are unable to complete the clinical development of our obtain marketing approval for our product candidates or successfully commercialize IGALMI and our other product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed."

4. Discussions with Analysts About TRANQUILITY II Trials

192. Defendants knew that investors were especially interested in the TRANQUILITY II trials and its progress.

193. Questions from analysts about the TRANQUILITY trials were frequent. On March 10, 2022, during BioXcel's 4Q21 earnings call, Robyn Kay Shelton Karnauskas, a research analyst from Truist Securities, Inc., asked, "So on TRANQUILITY I and II, are you planning on reading [at] the same time as you thought through how are you reading out and how you might disclose the data?" On August 9, 2022, during BioXcel's 2Q22 earnings call, Colin Nigel Bristow ("Bristow") from UBS Investment Bank stated, "it looks like TRANQUILITY 2 timing slipped a little from end of this year to first half of next. Just curious what's the rationale behind this." On

October 18, 2022, during the BioXcel Commercial Day call, Bristow asked Defendants, "to talk through just the broader opportunity that you see in dementia" to which Defendant Mehta responded that "Alzheimer's dementia is a very large opportunity. As you know that we have 2 ongoing trials going on. And we see that as very strategic to building our agitation franchise." Next, during BioXcel's 3Q22 earnings call, Yatin Suneja ("Suneja") with Guggenheim Partners mentioned TRANQUILITY trials and asked Defendants, "[c]ould you just frame for us the expectations for that study is going to be down in the first half of 2023, what do you expect to show?" During BioXcel's 4Q22 earnings call on March 9, 2023, Sumant Kulkarni from Canaccord asked Defendants in regard to TRANQUILITY II, "[w]hat is a typical timeline for data verification and cleaning for a relatively quick trial like this?" On May 8, 2023, during BioXcel's 1Q23 earnings call, Suneja asked, "[a] question on the TRANQUILITY II. So I think the primary endpoint is at day 1, but the study is 3 months. Could you maybe articulate for us how did you come up with the 3-month study, at least in the open label? What sort of regulatory discussions were? And then in terms of filing requirements, help us understand what would be needed. Just curious how did you come up with the – what the negotiation of back and forth was with the FDA when you were designing the II and III TRANQUILITY II and III studies."

194. In the face of frequent questions from analysts, Defendants would have expected and prepared for these questions from analysts about the TRANQUILITY trials during earnings calls and conferences. In Defendants' preparation for these analyst questions, they would have discovered the compliance violations at TRANQUILITY II's North Miami site and the resulting Form 483. Instead of disclosing the truth about TRANQUILITY II, Defendants chose to misrepresent the progress of the clinical trials to investors.

5. Defendant Mehta's and Risinger's Hands-On Involvement

195. Both Defendant Mehta and Defendant Risinger were described by the CWs as very involved in BioXcel and the progress of BXCL501. CW2 reported that Defendant Risinger was the person assigned to work with the monitor, i.e., Dr. Meyer, at Segal Trial's clinical trial site.

196. CW7 reported that Defendant Mehta was "very involved" in choosing sites and vendors for clinical operations. CW7 went on to describe Defendant Mehta as a very "hands-on CEO." According to CW7, Defendant Mehta was very active during meetings about BXCL501.

197. Moreover, CW5, who had worked directly with Defendant Risinger, reported that Risinger was "kind of monolithic" and that "he just ran everything." CW5 went on to state that Risinger made "all the development decisions … on a microscopic level."

198. Defendants Mehta's and Risinger's hands-on involvement at BioXcel means that they knew of the compliance violations that resulted in a Form 483 and how that would affect the filing of the NDA.

6. Defendants Signed Sarbanes-Oxley Certifications

199. Appended as exhibits to BioXcel's Form 10-K for the period ending December 31, 2021 and Form 10-K for the period ending December 31, 2022 were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Mehta and Steinhart certified that each 10-K "fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act] and that information contained in in Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

200. Moreover, both of the aforementioned 10-Ks also included additional certifications singed by Defendants Mehta and Steinhart that state:

> 1. I have reviewed this Annual Report on Form 10-K [] of BioXcel Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

B. MOTIVE AND OPPORTUNITY

201. The Individual Defendants, as well as other BioXcel insiders, had motive and opportunity to mislead investors for two reasons. First, BioXcel was receiving critical funding from private investors, which was contingent on the success of the TRANQUILITY II trial. Second, BioXcel insiders engaged in significant highly unusual and suspiciously timed insider trading during the Class Period, reaping millions of dollars in personal gains.

1. Funding from Investors

202. The Company was in weak financial health. It depended on loans from Oaktree and QIA to fund its operations, and BioXcel's ability to procure tranches of this funding was contingent on meeting certain performance milestones, including sales of BXCL501 and passing regulatory hurdles in securing FDA approval for BXCL501 to be indicated for Alzheimer's and dementia patients.

203. CW4, a former Associate Director of FP&A and Head of FP&A, who was employed by BioXcel until February 2023, stated that the Company was "burning cash." He was instructed to "provide a worksheet of different [financial] scenarios, like, if we would get additional funding from Oaktree." He further stated, "we were constantly analyzing how much we would get from Oaktree. We wanted to see how long we would last, if we didn't get funded."

204. Under the Company's financing agreements with Oaktree and QIA, BioXcel was set to receive up to $260 million in gross funding to support the Company's expansion of clinical developments of BXCL501, among others.

205. The financing agreements, in essence, consisted of: (1) a credit agreement for up to $135 million in a delayed draw term loan, (2) a revenue interest financing agreement for up to $120 million in a capped revenue interest on net sales of IGALMI and any other future BXCL501 products, and (3) up to $5 million purchase of the Company's common stock.

206. But BioXcel's ability to access all this funding depended on its ability to pass regulatory hurdles in securing FDA approval for BXCL501, as explained above in ¶¶ 74-86. CW1, a former Medical Strategy/Medical Director who was employed by BioXcel until October 2023, describes the effect of the funding agreements on the TRANQUILITY II Study. CW1 stated that "there were time pressures" associated with procuring data from TRANQUILITY II "because there were milestones to show investors." Specifically, the goal was to file a NDA application with the FDA by the end of 2023, which "meant the data analysis needed to start by July." CW1 reiterated that for at least one of Oaktree and QIA, "for the end of 2023, significant milestones . . . needed to be met, both for commercial sales and clinical studies. If not completed, either new funding wouldn't be available, or potentially, the company would have to kick back some money."

2. Unusual and Suspiciously Timed Insider Sales and Bonuses Tied to Performance

207. Defendants Mehta and Steinhart and Director Nandabalan engaged in stock sales during the Class Period that were suspiciously timed. As a result of these Class Period trades, these individuals profited from the artificially inflated price of BioXcel stock caused by their false and misleading statements and omissions to investors during the Class Period.

208. In evaluating the Individual Defendants' selling activity, Lead Plaintiffs utilized the publicly-available trading data that the Individual Defendants were required to report to the SEC through its Form 4. The Forms 4 filed during the Class Period are hereby incorporated by reference, and a summary of the relevant transactions are set forth below.

209. Defendant Mehta did not make any sales of shares of BioXcel stock prior to the Class Period.

210. During the Class Period, Defendant Mehta made the following transactions involving shares of BioXcel stock:

Date	Action	No. of Shares	Transaction Price per Share	Amount
12/15/2022	Exercised call options	30,000	$ 0.41	($ 12,300.00)
12/15/2022	Open market sale	22,794	$ 19.86	$ 452,688.84
	Open market sale	7,206	$ 20.19	$ 145,489.14
12/16/2022	Exercised call options	30,000	$ 0.41	($ 12,300.00)
	Open market sale	20,113	$ 19.21	$ 386,370.73
	Open market sale	9,887	$ 19.92	$ 196,949.04
3/14/2023	"Exercised" RSUs	10,437	$ 0.00	($ 0.00)
3/20/2023	Exercised call options	30,000	$ 0.41	($ 12,300.00)
3/20/2023	Open market sale	24,667	$ 18.20	$ 448,939.40
	Open market sale	5,333	$ 18.86	$ 100,580.38
	Open market sale	3,896	$ 18.22	$ 70,985.12
	Open market sale	604	$ 18.88	$ 11,403.52
3/21/2023	Exercised call options	30,000	$ 0.41	($ 12,300.00)
	Open market sale	29,100	$ 19.70	$ 573,270.00
	Open market sale	900	$ 20.15	$ 18,135.00
5/14/2023	"Exercised" RSUs	15,000	$ 0.00	($ 0.00)
5/22/2023	Open market sale	6,500	$ 25.79	$ 167,640.85
6/14/2023	"Exercised" RSUs	2,609	$ 0.00	($ 0.00)
6/15/2023	Exercised call options	30,000	$ 0.41	($ 12,300.00)
	Open market sale	21,988	$ 21.41	$ 470,763.08
	Open market sale	8,012	$ 21.90	$ 175,462.80
6/16/2023	"Exercised" RSUs	30,000	$ 0.41	($ 12,300.00)
	Open market sale	24,987	$ 20.01	$ 499,989.87
	Open market sale	4,266	$ 20.90	$ 89,159.40
	Open market sale	747	$ 21.89	$ 16,351.83
			TOTAL	**$ 3,750,379**

211. To be precise, Defendant Mehta sold 191,000 shares of BioXcel stock during the Class Period, yielding him a net profit of $3,750,379.00. Through these transactions, Defendant Mehta disposed of approximately 91.8% of the total shares, including stock units, he had available during the Class Period. Other than these, Defendant Mehta had not made any other direct sales of shares of BioXcel stock.

212. Defendant Mehta's total compensation for fiscal year 2022 was $4,559,195.

213. Similar to Defendant Mehta, Director Nandabalan employed the same selling technique during the Class Period. He would exercise his options and almost immediately sell all shares of BioXcel stock derived therefrom on the open market.

214. During the Class Period, Director Nandabalan made the following transactions involving shares of BioXcel stock:

Date	Action	No. of Shares	Transaction Price per Share	Amount
11/10/2022	Exercised call options	27,450	$ 0.41	($ 11,254.50)
11/10/2022	Open market sale	27,450	$ 15.00	$ 411,750.00
11/11/2022	Exercised call options	32,550	$ 0.41	($ 13,345.50)
11/11/2022	Open market sale	32,550	$ 15.00	$ 488,250.00
1/4/2023	Exercised call options	34,111	$ 0.41	($ 13,985.51)
1/4/2023	Open market sale	24,290	$ 21.59	$ 524,421.10
1/4/2023	Open market sale	9,821	$ 22.21	$ 218,124.41
1/5/2023	Exercised call options	25,899	$ 0.41	($ 10,618.59)
1/5/2023	Open market sale	25,089	$ 22.32	$ 559,986.48
1/5/2023	Open market sale	800	$ 22.93	$ 18,344.00
4/6/2023	Exercised call options	60,000	$ 0.41	($ 24,600.00)
4/6/2023	Open market sale	60,000	$ 17.32	$ 1,039,200.00
			TOTAL	**$ 3,186,271.89**

215. Director Nandabalan sold 180,000 shares of BioXcel stock during the Class Period, yielding him a net profit of $3,186.271.89. Through these transactions, he disposed of all the shares he directly owned during the Class Period. Other than these, Director Nandabalan had not made any other sales of shares of BioXcel stock.

216. Nandabalan did not receive compensation as a director of the Company in fiscal year 2022. Instead, as of December 31, 2022, he had received and held options to purchase 423,688 shares of BioXcel common stock, all of which were exercisable.

217. Prior to the Class Period, Defendant Steinhart had only sold his BioXcel stock on one occasion. On February 1, 2021, Defendant Steinhart exercised his options and purchased 3,750 shares of BioXcel stock at a strike price of $5.55 per share. He immediately sold all these shares in the open market at an average price of $48.15 per share, yielding him a profit of approximately $159,750.00.

218. During the Class Period, Defendant Steinhart made the following transactions involving shares of BioXcel stock:

Date	Action	No. of Shares	Transaction Price per Share	Amount
3/14/2023	"Exercised" RSUs	2,084	$ 0.00	($ 0.00)
3/15/2023	Open market sale	2,084	$ 19.50	$ 40,638.00
5/14/2023	"Exercised" RSUs	5,000	$ 0.00	($ 0.00)
5/15/2023	Open market sale	5,000	$ 27.17	$ 135,864
6/14/2032	"Exercised" RSUs	521	$ 0.00	($ 0.00)
			TOTAL	**$ 176,502**

219. Defendant Steinhart sold 7,084 shares of BioXcel stock during the Class Period, yielding him a net profit of $176,501.50. Through these transactions, Defendant Steinhart disposed of approximately 93.1% of the total shares, including stock units, he had available during the Class Period. Other than these, Defendant Steinhart had not made any other sales of shares of BioXcel stock.

220. The foregoing sales of BioXcel stock were made pursuant to 10b5-1 trading plans that were entered into shortly before the Class Period. Defendant Mehta and Director Nandabalan's trading plans were entered into on August 31, 2022, at a time when they were well-aware of adverse material nonpublic information. Defendant Steinhart entered into a 10b5-1 trading plan on June 23, 2022.

221. Such sales by Defendants Mehta and Steinhart and Director Nandabalan therefore support a strong finding of scienter.

222. Moreover, according to the Company's executive compensation plan, Defendant Mehta as well as other executive officers stood to gain annual bonuses upon achieving certain performance goals, which generally related to clinical trial performance, and completing certain financial and operational objectives, as well as an assessment of individual performance. In fact, Defendant Mehta received a bonus in the amount of $150,000 for the strategic financing agreements with Oaktree and QIA for fiscal year 2022.

VIII. CLASS ACTION ALLEGATIONS

223. Lead Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired BioXcel common stock during Class Period of the December 7, 2022 through August 11, 2023, both dates inclusive and were damaged thereby. 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.

224. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, shares of BioXcel common stock actively traded on the NYSE. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can be ascertained only through appropriate discovery, Lead Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. 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.

225. 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 misrepresented material facts about the business, operations and management of BioXcel;

(c) whether the Individual Defendants caused BioXcel to make false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the Defendants' conduct complained of herein artificially inflated the prices of BioXcel securities during the Class Period; and

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

226. Lead Plaintiffs' 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.

227. Lead Plaintiffs 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. Lead Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

228. 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.

IX. PRESUMPTION OF RELIANCE

229. At all relevant times, the market for BioXcel's common stock was open, well-developed, and efficient, for the following reasons, among others:

(a) BioXcel's common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

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

(c) BioXcel regularly and publicly communicated with investors via established market communication channels, including through the 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 analysts employed by brokerage firms who issued reports about the Company and these reports were distributes to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

230. As a result of Defendants' materially false and misleading statements, BioXcel's common stock traded at artificially inflated prices during the Class Period. Lead Plaintiffs and other members of the Class purchased or otherwise acquired the Company's common stock relying upon the integrity of the market price of BioXcel's common stock and market information relating to BioXcel, and have been damaged thereby.

231. As a result of the foregoing, the market for BioXcel's common stock 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 common stock during the Class Period suffered similar injury through their purchase of BioXcel's common stock at artificially inflated prices and a presumption of reliance applies.

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

because the Class's claims are, in part, grounded on certain of Defendants' that were misleading because they omitted to disclose the contents of the Form 483 Letter. Because Defendants' failure to disclose material adverse information regarding the TRANQUILITY II Study as well as information concerning Defendants' financing agreements and overall financial health – 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.

X. INAPPLICABILITY OF STATUTORY SAFE HARBOR

233. The statutory safe harbor provided for forward-looking statements under certain circumstances is inapplicable to the false statements alleged in this Amended Complaint. The statements alleged to be false herein all related to then-existing facts and conditions. Further, to the extent that certain of the statements alleged to be false may be characterized as forward looking, they were not characterized as "forward-looking statements" when made and there was no meaningful cautionary language 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, 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.

XI. LOSS CAUSATION

234. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiffs and the Class.

235. During the Class Period, Lead Plaintiffs and the Class purchased BioXcel common stock at artificially inflated prices and were damaged thereby. The price of the Company's common stock 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. The decline in the price of BioXcel's common stock was the direct result of Defendants' fraud finally being revealed to investors and the market.

236. The timing and magnitude of the declines in price of BioXcel common stock were not caused by changed market conditions, macroeconomic or industry factors, or non-BioXcel specific facts unrelated to Defendants' fraudulent conduct.

XII. COUNTS

COUNT I
For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Against All Defendants

237. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

238. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and did (i) deceive the investing public, including Lead Plaintiff and other Class members, as alleged herein; and (ii) cause Lead Plaintiff and other Class members to purchase BioXcel 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.

239. Defendants (i) knowingly or recklessly engaged in acts transactions, practices and courses of business in order to defraud Lead Plaintiff and the Class members; (ii) made various

untrue statements of material facts; and (iii) engaged in devices, schemes and artifices to defraud in connection with the purchase and sale of securities. All Defendants named are sued either as primary participants in the illegal conduct charged herein or as controlling persons as alleged below.

240. During the Class Period, Defendants made false statements which they knew to be or recklessly disregarded the truth that they were false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Specifically:

i. Mehta: Defendant Mehta made, or caused BioXcel to make, the false statements specified in ¶¶ 144, 147, 149, 151, 154, 156, 162, 169, 171, and 173 above.

ii. Steinhart: Defendant Steinhart made, or caused BioXcel to make, the false statements specified in ¶¶ 151, 154, 158, 164, and 169 above.

iii. Risinger: Defendant Risinger made, or caused BioXcel to make, the false statements specified in ¶¶ 160, 166, 167, 175 above.

iv. BioXcel: Defendant BioXcel is responsible for all of the false statements specified in Section VI, above.

241. Each of the Defendants engaged and participated in the continuous conduct to conceal material information about BioXcel's ability to properly reserve for losses as specified herein. Defendants directly or indirectly issued quarterly and annual reports, SEC filings, press releases and other statements and documents, including statements made to securities analysts and the media that influenced the market for BioXcel's securities. Such statements were materially

false and misleading in that they concealed the truth about BioXcel's finances and business prospects.

242. Defendants had actual knowledge of the materially false and misleading statements 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. Defendants committed said acts willfully or with reckless disregard for the truth. Additionally, each Defendant knew or recklessly disregarded the truth that material facts were being misrepresented as detailed above.

243. Evidence that Defendants acted knowingly or with reckless disregard for the truth lies within Defendants' knowledge and control. As the senior managers and/or directors of BioXcel, each of the Defendants (i) had control over the Company's public statements and filings; (ii) were privy to the creation and reporting of the Company's public filings; and (iii) had knowledge of the Company's dissemination of false information to investors, which they knew and/or recklessly disregarded was materially false.

244. The Individual Defendants are both directly and indirectly liable for the wrongs complained of herein. As a result of the dissemination of the false and misleading reports, filings, and releases, the market price of BioXcel securities was artificially inflated during the Class Period. Unbeknownst to them, Lead Plaintiffs and other members of the Class purchased or acquired securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

245. During the Class Period, Lead Plaintiffs and other members of the Class were unaware of the falsity of BioXcel's misrepresentations. Had they known the truth, they would not

have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflate prices that were paid.

246. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act.

247. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against Defendants Mehta, Steinhart, and Risinger

248. Lead Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

249. Defendants Mehta, Steinhart, and Risinger were controlling persons of BioXcel within the meaning of Section 20(a) of the Exchange Act as alleged herein. Due to their senior positions, each of the Defendants knew the adverse non-public information about BioXcel's misstatements about its reserves and false financial statements.

250. As officers and/or directors or a publicly owned company, Defendants Mehta, Steinhart, and Risinger had a duty to disseminate accurate and truthful information with respect to BioXcel's financial condition and results or operations. Defendants Mehta, Steinhart, and Risinger also had a duty to correct any materially false or misleading public statements issued by BioXcel.

251. During the Class Period, Defendants Mehta, Steinhart, and Risinger exercised their power and authority to cause BioXcel to engage in the wrongful acts complained of herein. In this capacity, they participated in unlawful conduct alleged which artificially inflated the market price of BioXcel securities.

252. By reason of the above conduct, Defendants Mehta, Steinhart, and Risinger are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by BioXcel.

XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs demand judgment against Defendants as follows:

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

(b) Requiring Defendants to pay compensatory damages to Lead Plaintiff and the Class for all damages caused by Defendants' wrongdoing;

(c) Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

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

XIV. DEMAND FOR TRIAL BY JURY

Lead Plaintiffs hereby demand a trial by jury.

Dated: December 5, 2023

Respectfully submitted,

LEVI & KORSINSKY, LLP

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