UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

individually and on behalf of all others similarly situated, Plaintiff, v. BIOVIE INC., CUONG DO, JOANNE WENDY KIM, and JOSEPH PALUMBO, Defendants.	**Case No.** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding BioVie Inc. ("BioVie," or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded BioVie securities from August 5, 2021 through November 29, 2023, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

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

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

4. Venue is proper in this Judicial District pursuant to Section 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). The Company is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

5. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

6. Plaintiff, as set forth in the attached Certification, purchased or otherwise acquired BioVie securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

7. Defendant BioVie is a clinical stage biopharmaceutical company that purports to engage in the discovery, development, and commercialization of innovative drugs therapies, including for treatment of neurological and neurodegenerative disorders and advanced liver disease. BioVie is incorporated in Nevada and its headquarters are located at 680 W. Nye Lane, Suite 201, Carson City, NV, 89703. The Company's stock trades on the NASDAQ under the ticker symbol "BIVI."

8. Defendant Cuong Do ("Do") has served as the Company's President and Chief Executive Officer since April of 2021, and throughout the Class Period.

9. Defendant Joanne Wendy Kim ("Kim") has served as the Company's Chief Financial Officer since October 1, 2018, and throughout the Class Period.

10. Defendant Joseph Palumbo ("Palumbo") has served as the Company's Executive Vice President and Chief Medical Officer ("CMO") since November 1, 2021, and throughout the Class Period.

11. Defendants Do, Kim and Palumbo, are sometimes referred to herein collectively as the "Individual Defendants."

12. The Individual Defendants directly participated in the management of the Company and/or were directly involved in the day-to-day operations of the Company at the highest levels.

13. The Individual Defendants possessed the power and authority to control the contents of the Company's SEC filings, press releases, and other market communications. The Individual

Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

14. BioVie is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

15. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to BioVie under respondeat superior and agency principles.

16. BioVie and the Individual Defendants are referred to herein collectively as "Defendants."

BACKGROUND

17. Prior to the Class Period, in its 10-Q filed with the SEC on May 10, 2021, BioVie disclosed that on April 27, 2021, it had entered into a Purchase Agreement with related party entities NeurMedix and Acuitas, and had acquired certain assets "including NE3107, a small molecule orally administered inhibitor of insulin resistance and the pathological inflammatory cascade, with a novel mechanism of action that has potential applications for treatment against Alzheimer's Disease and Parkinson's Disease."

18. BioVie provided details on the transaction, stating:

> At the closing of the Transaction, BioVie will issue to NeurMedix 8,361,308 shares of the Company's common stock and make a cash payment equal to the aggregate amount of NeurMedix's direct and documented cash expenditures to advance certain clinical programs from March 1, 2021 through the closing, which cash payment is estimated to be approximately $3.0 million. Subject to the terms and

> conditions of the Purchase Agreement, following the closing, BioVie will also be obligated to deliver contingent consideration to NeurMedix (or its successor) consisting of (i) a cash payment of approximately $7.3 million, subject to a pivotal clinical trial for NE3107 meeting its primary endpoint(s) and BioVie having successfully raised at least $50 million in new capital, and (ii) shares of BioVie's common stock having an aggregate value of up to $3.0 billion, subject to the achievement of certain clinical, regulatory and commercial milestones related to the drug candidates to be acquired by the Company from NeurMedix, as more fully set forth in the Purchase Agreement.

19. BioVie further disclosed that:

> On May 9, 2021, the Company, NeurMedix and Acuitas entered into Amendment No. 1 to the APA (the "Amendment" and the APA as so amended, the "Purchase Agreement"), pursuant to which the parties agreed, among other things, to modify the contingent stock consideration that BioVie may be obligated to deliver to NeurMedix (or its successor) pursuant to the Purchase Agreement. Previously, BioVie was obligated to deliver contingent stock consideration to NeurMedix (or its successor) consisting of shares of BioVie's common stock having an aggregate value of up to $3.0 billion, subject to the achievement of certain clinical, regulatory and commercial milestones related to the drug candidates to be acquired by BioVie from NeurMedix, and subject to a cap limiting each issuance of shares if such issuance would result in the beneficial ownership of NeurMedix and its affiliates exceeding 89.9999% of BioVie's issued and outstanding common stock. Pursuant to the Amendment, BioVie will be obligated to deliver contingent stock consideration to NeurMedix (or its successor) consisting of up to 18.0 million shares of BioVie's common stock, with 4.5 million shares issuable upon the achievement of each of the four milestones set forth in the Purchase Agreement, subject to a cap limiting the issuance of shares if such issuance would result in the beneficial ownership of NeurMedix and its affiliates exceeding 87.5% of BioVie's issued and outstanding common stock.

20. On May 20, 2021, BioVie filed a Notice of Stockholder Action by Written Consent and an accompanying Information Statement on Form 14C providing additional details regarding the acquisition of NeurMedix.

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements

21. The Class Period starts on August 5, 2021, when BioVie announced in a Form 8-K filed with the SEC the enrollment of the first patient in its Phase 3 study of NE3107 in Alzheimer's Disease. BioVie stated:[1]

> BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug candidates for the treatment of neurological and neurodegenerative disorders, liver disease and certain cancers, today announced that ***the Company has enrolled the first patient into the NM101 Phase III clinical study testing NE3107 for the treatment of Alzheimer's Disease (AD).***
>
> The NM101 study (NCT04669028) is a potentially pivotal Phase 3, randomized, double blind, placebo-controlled, US multicenter study of NE3107 in 316 subjects with mild to moderate AD. In addition to conventional cognition, memory, functional, behavioral and imaging end points, NM101 will assess measures of glycemic control, brain glucose utilization and systems dysregulation. ….

22. On August 30, 2021, the Company filed its annual report on Form 10-K, which was signed by Defendants Do and Kim (the "2020 10-K"). In the 2020 10-K the Company represented that:

> The FDA has authorized a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). ***BioVie is planning to initiate this trial in the second half of 2021 and is targeting primary completion in late 2022.***

23. On November 10, 2021, BioVie filed its quarterly report with the SEC on Form 10-Q for the quarter ended September 30, 2021 (the "1Q 2021 10-Q"). The 1Q 2021 10-Q was signed by Defendants Do and Kim. In the filing the Company described its acquisition of certain assets from NeurMedix and further disclosed that:

> The FDA has authorized a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). ***In***

[1] Unless otherwise noted, all statements that have been italicized and/or bolded have had emphasis added.

> ***August 2021, the study was initiated and the Company is anticipating top line results in late calendar year 2022***.

24. On February 7, 2022, BioVie filed its quarterly report with the SEC on Form 10-Q for the quarter ended December 31, 2021 (the "2Q 2021 10-Q"). The 2Q 2021 10-Q was signed by Defendants Do and Kim, and provided an update on the timing of the Phase 3 clinical trial:

> The FDA has authorized a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). ***We initiated this trial on August 5, 2021 and are targeting primary completion in the first half of 2023.***

25. On May 11, 2022, BioVie filed its quarterly report with the SEC on Form 10-Q for the quarter ended March 31, 2022 (the "3Q 2021 10-Q"). The 3Q 2021 10-Q was signed by Defendants Do and Kim and contained identical representations regarding the acquisition of assets from NeurMedix and the ongoing Phase 3 clinical trial of NE3107 for subjects with mild to moderate Alzheimer's disease.

26. On June 29, 2022, BioVie filed an Investor Presentation accompanying a Form 8-K, which was signed by Defendant Kim. The Investor Presentation provided a description of the Phase 3 clinical trial, the mechanism of action for the drug candidate, as well as an update. The Investor Presentation specifically noted that "***Phase 3 patient enrollment is underway; ramping to 45 centers; data readout anticipated mid-2023***." The slide further noted that the drug had ***"$10+ billion annual peak sales potential***."

27. On September 7, 2022, BioVie filed a press release and slide presentation on Form 8-K, which was signed by Defendant Kim. The Form 8-K provided an update on the Phase 3 clinical trial, stating:

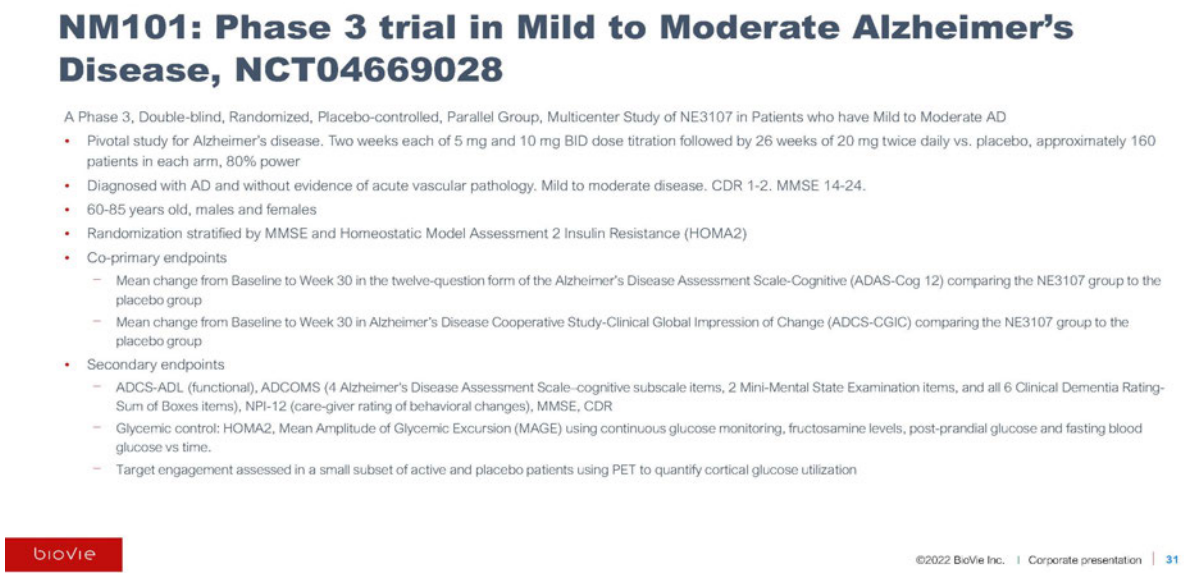
> ***The potentially pivotal Phase 3 trial for NE3107 in AD (NCT04669028) has enrolled one-half of the targeted 316 patients.*** In blinded data, no drug-related adverse events have been seen in daily medical reviews. The study pre-specified the potential to increase enrollment up to 400 patients as deemed appropriate through a review by the data safety monitoring board (DSMB) in a manner that is

blinded to the Company. This DSMB review will take place later this year and will determine if a sample size adjustment is needed for the purpose of enhancing the probability of achieving statistical significance. ***If no sample size adjustments are needed, the Company expects full enrollment of the study by the end of the year, enabling topline data readout by mid-2023.*** The study may be delayed if additional patients need to be enrolled in the event of a DSMB recommendation.

28. The accompanying press release to the Form 8-K added:

Furthermore, NE3107 is the only molecule in the group that ***is conducting a potentially pivotal Phase 3 trial (NCT04669028) that is currently underway in mild- to moderate-AD patients*** with co-primary endpoints of cognition, as measured by the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog12), and function, as measured by Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC), whereas 17 other agents are in Phase 2. ***This Phase 3 trial is expected to provide topline results in mid-2023.***

29. The accompanying slide presentation to the Form 8-K filed on September 7, 2022 provided a description of the Phase 3 clinical trial as well as an update. The Company specifically noted in the presentation that the trial had "***enrolled one-half of targeted patients***" and that "***no drug-related adverse events have been seen in daily medical reviews.***" The update also stated that "DSMB will review data later this year to recommend whether the company should increase study size beyond targeted 316 patients." The following slide described the clinical trial:



30. On September 27, 2022, BioVie filed its annual report on Form 10-K, which was signed by Defendants Do and Kim (the "2021 10-K"). In the 2021 10-K the Company stated:

> The FDA has authorized a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). ***We initiated this trial on August 5, 2021 and are targeting primary completion in mid calendar year of 2023.***

31. On October 4, 2022, BioVie filed a press release on Form 8-K, which was signed by Defendant Kim. The press release incorporated a letter to shareholders and was signed by Defendant Do. The letter stated that "**Potentially pivotal Phase 3 trial for NE3107 in Alzheimer's has enrolled over half the targeted patients and is on track to readout mid-2023."** (emphasis in original). Defendant Do concluded the letter by saying:

> ***Overall, we are very excited with the progress of our clinical programs and the progress towards the potential of advancing meaningful therapies for our patient communities.*** We expect to provide two significant data updates later this year: 1) the full data presentations from the investigator-sponsored exploratory biomarker study at CTAD; and 2) topline data readout from the Parkinson's Phase 2 before year-end. ***We are also looking forward to an exciting 2023 as we finalize the Alzheimer's Phase 3 and the ascites Phase 2b, both of which are expected roughly mid-year***.

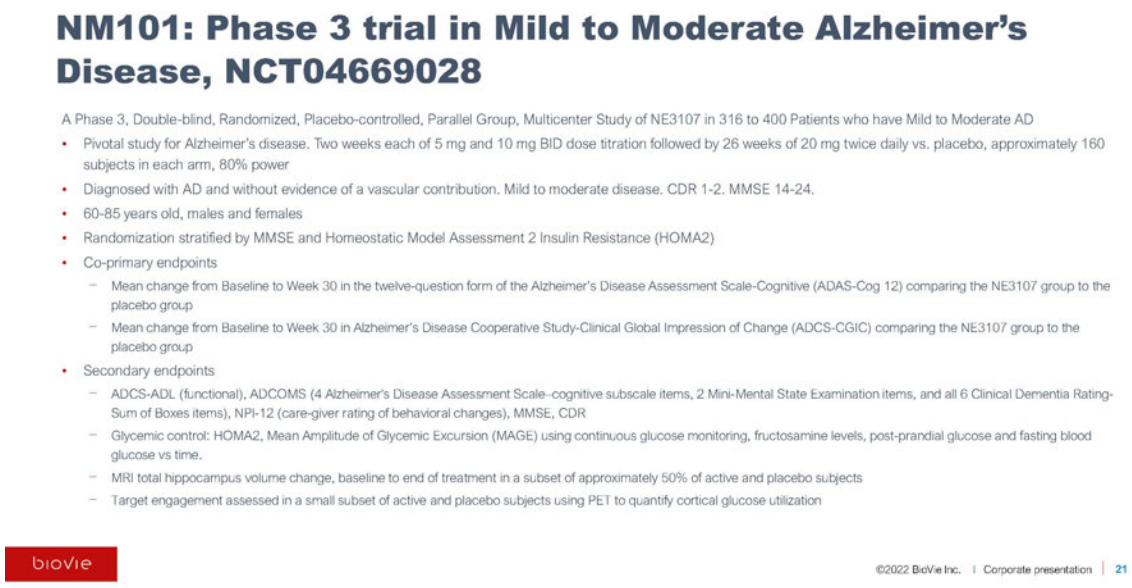
32. On November 4, 2022, BioVie filed its quarterly report with the SEC on Form 10-Q for the quarter ended September 30, 2022 (the "1Q 2022 10-Q"). The 1Q 2022 10-Q was signed by Defendants Do and Kim. In the filing the Company described NE3107's properties and the design of the Phase 3 clinical trial in identical terms as the 3Q 2021 10-Q and the 2021 10-K, and further disclosed that:

> The Neuroscience NE3107 studies accounted for approximately $3.9 million of the net increase in research and development expenses as ***both studies were significantly more active during the three months ended September 30, 2022 over the three months ended September 30, 2021, as the. . . . Alzheimer Phase 3 study nears full enrollment.***

33. On December 7, 2022, the Company filed a Form 8-K, which was signed by Defendant Kim and accompanied by a press release and Investor Presentation. The Investor Presentation provided background on the development of NE3107, its mechanism of action and applications, indicated that more than 316 patients were enrolled in the Phase 3 clinical trial and that data readout

was anticipated in mid-2023. The presentation also indicated that the drug candidate had ***"$10+ billion annual peak sales potential."***

34. The Investor Presentation also provided a slide specifically discussing the status of the Phase 3 clinical trial:



35. On February 10, 2023, BioVie filed its quarterly report with the SEC on Form 10-Q for the quarter ended December 31, 2022 (the "2Q 2022 10-Q"). The 2Q 2022 10-Q was signed by Defendants Do and Kim. The 2Q 2022 10-Q described in identical terms to the 1Q 2022 10-Q the properties of NE3107 and the design of the Phase 3 clinical trial. The 2Q 2022 10-Q also provided an update on the clinical trial's progress, stating:

> In August 2021, the Company initiated the FDA authorized potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate AD (NCT04669028). ***The Company is targeting primary completion of this study in the third quarter of calendar year 2023.***

36. The Company also disclosed that:

> The increase in research and development expenses of $1.3 million was primarily due to the Neuroscience NE3107 studies, which were significantly more active during the three months ended December 31, 2022 compared to the three months ended December 31, 2021. . . . ***[T]he Alzheimer Phase 3 study is approaching full enrollment.***

37. On March 23, 2023, BioVie filed an Investor Presentation on Form 8-K, which was signed by Defendant Kim. The Investor Presentation discussed NE3107 and the Phase 3 clinical trial. A slide providing an overview of the Company's Alzheimer's Disease program indicated: "NM101 Phase 3 in mild- to moderate-AD fully enrolled. Last patient visit expected in September 2023. Topline data readout expected October 2023."

38. A later slide indicated that the "[t]rial continues to have a good safety profile and low discontinuation rate," and that "[b]linded baseline data shows evidence of metabolic inflammation in amyloid ß positive and negative, and APOEε4 positive and negative subjects submitted for presentation at the American Diabetes Association's 83rd Scientific Sessions in San Diego, June 23-26, 2023."

39. Another slide on the presentation provided an "Update on NM101 Phase 3 in Mild/Moderate." The slide indicated that the trial was fully enrolled as of February 28, 2023, that 100 patients had completed treatment, and that a top-line data readout was expected in October 2023.

40. On May 12, 2023, the Company filed its quarterly report with the SEC on Form 10-Q for the quarter ended March 31, 2022 (the "3Q 2022 10-Q"). The 3Q 2022 10-Q was signed by Defendants Do and Kim. In the filing the Company described NE3107's properties and the design of the Phase 3 clinical trial in identical terms as the 1Q and 2Q 2022 10-Qs and provided an update on the timing of the clinical trial. The Company stated:

> In August 2021, the Company initiated the FDA authorized potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate AD (NCT04669028). ***The Company is targeting primary completion of this study in the fourth quarter of calendar year 2023.***

41. BioVie also disclosed that:

> The increase in research and development expenses of approximately $6.7 million was primarily due to the Neuroscience NE3107 studies, which were significantly more active during the three months ended March 31, 2023, compared to the three

months ended March 31, 2022. . . . ***[T]he Alzheimer Phase 3 study reached full enrollment***.

42. The statements in ¶¶21-41 were materially false and/or misleading because Defendants knew, or recklessly disregarded, and failed to disclose material adverse facts, including: (1) that the ongoing COVID-19 pandemic caused "limited access" to clinical trial sites, significantly affecting the Company's ability to conduct proper oversight of the clinical trial; and (2) due to the "limited access" to the clinical trial sites, the trial was at higher risk of having "significant deviation from protocol and Good Clinical Practice (GCP) violations" and "anomalous data."

43. On August 16, 2023, the Company filed its Annual Report on Form 10-K, which was signed by Defendants Do and Kim (the "2022 10-K"). The 2022 10-K stated:

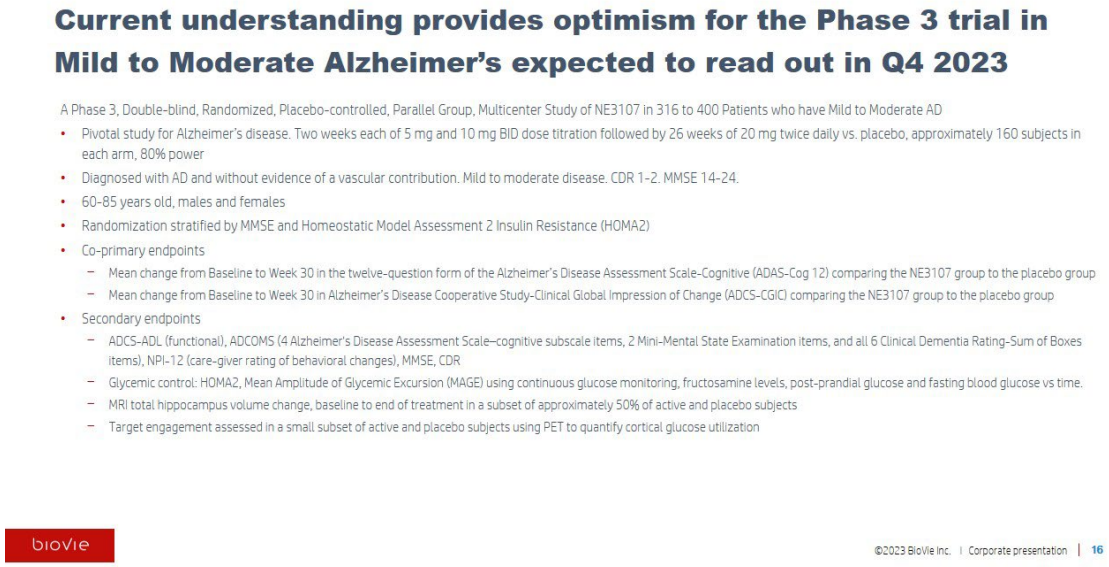
> The Company is conducting a potentially pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in patients who have mild to moderate AD (NCT04669028) . . . . ***The program is fully enrolled and is targeting primary completion in the fourth quarter of the calendar 2023 year.***

44. The 2022 10-K contained a new risk disclosure regarding use of contract research organizations to conduct clinical trials as it relates to current good clinical practices. The new warning read as follows:

> **We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. (emphasis in original).**
>
> We depend, and will continue to depend, on contract research organizations ("CROs"), clinical trial sites and clinical trial principal investigators, contract laboratories, and other third parties to conduct our clinical trials**.** We rely heavily on these third parties over the course of our clinical trials, and ***we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third parties does not relieve us of our regulatory responsibilities.*** We and these third parties are required to comply with current good clinical practices ("cGCPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development. Regulatory authorities enforce cGCPs through periodic inspections and for-cause inspections of clinical trial principal

investigators and trial sites. ***If we or any of these third parties fail to comply with applicable cGCPs or fail to enroll a sufficient number of patients, we may be required to conduct additional clinical trials to support our marketing applications, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state, or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or provide us or government agencies with inaccurate, misleading, or incomplete data.***

45. On September 8, 2023, BioVie filed an Investor Presentation on Form 8-K, which was signed by Defendant Kim. The Investor presentation discussed NE3107 and the Phase 3 clinical trial, stating:



46. On October 25, 2023, BioVie filed a press release on Form 8-K, which was signed by Defendant Kim. The headline of the press release was "**Blinded Data Presented at CTAD Suggest that NE3107 is Biologically Active and May Have Impact on Cognitive, Biomarker, and Imaging Endpoints Among Mild to Moderate Alzheimer's Disease Patients.**" (emphasis in original). In discussing the results of the recently completed Phase 3 clinical trial, the press release stated as follows:

The blinded data presented suggest that NE3107 is a biologically active compound exerting potential effects as observed by biomarker, imaging, cognitive and functional assessments. ***Population changes from baseline were observed, with some patients demonstrating an improvement after 30 weeks of treatment with***

the double blinded oral study drug (NE3107 or matched placebo) as compared to baseline, while many were also observed to have worsened, which is consistent with the natural progression of the disease (Figure 1).

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The rate and nature of adverse events in the blinded data appear consistent with prior clinical studies of NE3107.

"The blinded data presented at CTAD show encouraging changes from baseline that would not typically be seen without a treatment effect, which provides us with confidence that NE3107 may show a clear benefit over placebo when the data from this trial is unblinded in the coming weeks," commented Joseph Palumbo, BioVie's Chief Medical Officer. "We believe NE3107 has the potential become to effective multi-mechanistic treatment for Alzheimer's that is safe and can be orally administered."

The last patient came in for the last treatment visit in late September 2023, and the Company is currently resolving outstanding database queries and preparing for database freeze and data unblinding. The Company expects to announce unblinded, topline data from this trial in the November/December timeframe.

47. The statements in ¶¶43-46 were materially false and/or misleading because Defendants knew, or recklessly disregarded, and failed to disclose material adverse facts, including: (1) that the ongoing COVID-19 pandemic caused "limited access" to clinical trial sites, significantly affecting the Company's ability to conduct proper oversight of the clinical trial; and (2) due to the "limited access" to the clinical trial sites, the trial was at higher risk of having "significant deviation from protocol and Good Clinical Practice (GCP) violations" and "anomalous data;" (3) that the Company was already experiencing issues with the contract research organization ("CRO") it had retained, creating greater risk of the trial being in non-compliance with GCPs; and (4) the Company had already identified "higher than expected levels of deviations" in the data.

48. On November 1, 2023, BioVie hosted a conference call to discuss the Phase 3 trial. The call was attended by analysts and hosted by Defendants Do and Palumbo, as well as Dr. Steven Arnold. During opening remarks Defendant Do stated:

So we presented the data that we had as of October 18 from roughly 322 subjects, whose data were verified or in the process of being verified and cleaned as of this date.

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And in looking at the totality of the data, we conclude that any NE3107 appears to be biologically active and that it appears to be having an impact on the cognitive biomarkers and end-to-end points that we've looked at in the trial.

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And as we look at this pattern, we see great -- ***we have some optimism that there is an effect, a drug effect going on.*** We need to make that comment because if there were not a drug effect, you would expect all the subjects to be clumped together. And that would be roughly around the no-change line or it's somewhat worsening, somewhat getting better if there's a learning or a placebo effect.

But the fact that we see a pattern of maybe people getting better and many people getting worse, which suggests to us that there is something going on beyond just a group, the drug that not working. You would not see a lot of people getting a lot better if there is not something going on here, right? ***And the magnitude of the clinical getting better from this blinded data is a little too large from what you would expect from just a placebo effect.***

49. Defendant Palumbo followed up with additional comments on the Phase 3 clinical trial, stating:

So [the results tell] us that we've captured the right individuals for this study. It shows that in the course of only six months, who started out as negative shift, towards positive, it gives us a good look at the sensitivity of this study. And that -- and remember, half of these folks are on drug and half are on placebo.

So for me, this is a signal I was looking for in the midst of COVID, in the midst of everything else. Did we capture the right patients and would they progress as expected, right? And you wouldn't necessarily see this in a study that was only looking at positive patients at baseline. Now the data and positivity is great, of course, that we have people who shift towards this negative status, and that is absolutely exciting.

Also, this validation study is long enough, at least to me, in looking at the shift from negative to positive in a six-month basis of the study. And so I'm actually very happy with that. And that was all I really wanted to say, Cuong.

50. During the question-and-answer session Defendant Do stated:

So with that, I know that we have over time here, let me close the call by saying that we are cautiously optimistic when looking at the totality of the data, right? And I do not believe you can look at any one particular measure to say things are working or not working, you have to look at the totality of the data.

And the totality of the data here would suggest that NE3107 appears to have an underlying biological effect and that biological effect appears to be having an impact on the cognitive, functional, biomarker and imaging endpoints that we are looking at in this trial.

So we are cautiously optimistic that when we unblind the data after Thanksgiving or early December, that this could potentially lead to a significant improvement,

a significant new tool for the community to treat Alzheimer's disease when it's fully registered.

51. The statements contained in ¶¶48-50 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to BioVie's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the ongoing COVID-19 pandemic caused "limited access" to clinical trial sites, significantly affecting the Company's ability to conduct proper oversight of the clinical trial; (2) due to the "limited access" to the clinical trial sites, the trial was at higher risk of having "significant deviation from protocol and Good Clinical Practice (GCP) violations" and "anomalous data;" (3) the Company was experiencing issues with the CRO(s) it had retained, creating greater risk of the trial being in non-compliance with GCPs; (4) the Company had identified "higher than expected levels of deviations" in the data; (5) due to a "highly unusual level of suspected improprieties" there was a heightened risk a majority of the clinical trial subjects would be excluded; (6) as a result of the exclusions, there was a heightened material risk that the clinical trial would "not achieve statistical significance;" and (7) as a result of the foregoing, statements about BioVie's business, operations, prospects, and/or compliance with GCP were materially false and/or misleading and/or lacked a reasonable basis at all relevant times.

The Truth Begins To Emerge

52. On November 8, 2023, the Company filed its quarterly report with the SEC on Form 10-Q for the quarter ended September 30, 2023 (the "1Q 2023 10-Q"). The 1Q 2023 10-Q was signed by Defendants Do and Kim. In the filing the Company described NE3107's properties and the design of the Phase 3 clinical trial in identical terms as the 3Q 2021 10-Q and the 2021 10-K, and further disclosed that:

> Late in September 2023, the final patient completed the last treatment at week 30 in the Company's multicenter, randomized, double-blind, placebo-controlled Phase

3 study (NCT04669028) of NE3107 in patients who have mild to moderate Alzheimer's disease. The database cleaning process remains underway, with the clinical team resolving outstanding queries and entering final data into the electronic data system. Final database lock, unblinding and subsequent release of topline results is anticipated to occur during the fourth quarter of calendar year 2023.

53. BioVie also stated that:

[D]uring routine monitoring of blinded data from our Phase 3 study (NCT04669028) of NE3107, ***we uncovered what appears to be potential scientific misconduct and significant non-compliance with GCPs and regulation at six sites***. We have alerted the FDA's Office of Scientific Integrity ("OSI") about these issues and believe OSI will perform a thorough, competent, objective and fair research of any potential scientific misconduct and non-compliance of GCPs and regulation. ***Sensitivity analysis excluding data from these six problematic sites has been performed and accounted for in the statistical analysis plan for the study*** (NCT04669028). Nonetheless, ***these findings of potential scientific misconduct and significant GCP violations may call into question the rigor, robustness and validity of the entire data set for this study (NCT04669028) and may require additional clinical studies to confirm the final results of the study***.

54. On November 9, 2023, the price of BioVie stock fell to a low of $2.31 per share, down from its closing price of $4.26 the day before. However, BioVie's stock price remained artificially inflated as a result of Defendants' failure to disclose the full extent of the adverse findings regarding the scientific misconduct and significant non-compliance with good clinical practices and regulations.

55. On November 29, 2023, BioVie filed a Form 8-K, which was signed by Defendant Kim. The Form 8-K indicated the Company "issued a press release and posted on its website at https://BioViepharma.com/ an investor presentation disclosing top line data from its clinical trial of NE3107 in the treatment of mild to moderate Alzheimer's Disease."

56. The press release accompanying the Form 8-K disclosed that:

The trial started during the COVID-19 pandemic when access to clinical sites was limited and enrolled a total of 439 patients through 39 sites. Upon trial completion, ***the Company found significant deviation from protocol and Good Clinical Practice (GCP) violations at 15 sites (virtually all of which were from one geographic area). This highly unusual level of suspected improprieties led the Company to exclude all patients from these sites*** and to refer them to the U.S. Food and Drug Administration (FDA) Office of Scientific Investigations (OSI) for further action. After these exclusions, 81 patients remained in our Modified Intent to Treat (MITT) population, 57 of whom were in the Per-Protocol population which

included those who completed the trial and were verified to take study drug from pharmacokinetic (PK) data.

57. The Investor Presentation that accompanied the Form 8-K provided further information about the "significant deviation from protocol" mentioned in the press release. Specifically, one of the slides indicated that:

- The Company monitors blinded data to track safety and ensure timely data entry into the EDC

- ***The company started noticing unusual data patterns when enough patients completed the trial***. Pentara (a leading AD biostatistics firm) reviewed the blinded data and found:

    - Several sites had anomalous data (e.g. inconsistent patterns compared to historical data, large proportions of patients improving compared to baseline, unusual variability patterns)

    - All patients in a particular demographic group enrolled in this trial showed a data pattern not explainable based on disease progression and which substantially deviated from historical data far this demographic in other AD trials

    - Without unblinding and PK data, there was no way to identify the cause. Clear subgroup analyses identified: anomalous sites vs. other sites; identified demographic group vs. all others

- In parallel, ***BioVie had the first opportunity to start the data review process as sites started to finish patient-facing activities in early summer 2023***

    - Noticed deviations from expectations (e.g. data patterns, missing data, copied/pasted MRI results, etc.)

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- ***CROs identified six sites with numerous and significant procedural deviations***, which led us to:

    - Updated SAP to 1) exclude all patients from affected sites; and 2) pre-specify a series of subgroup analyses

    - Amended our protocol: 1) Finalize CDR-SB and ADAS-Cog12 as primary endpoints based on prior FDA communications; 2) Created "adaptive trial" design

    - Reported the 6 sites to the FDA's Office of Scientific Investigations

- As data was unblinded, ***anomalous data from the identified demographic group was confirmed to be scientifically improbable***. Furthermore, ***all patients in***

> ***this demographic were associated with the previously identified anomalous sites***, and virtually all of which were concentrated in a single geographic area. Accordingly, these sites were also excluded per our SAP and additionally referred to the FDA.

58. The presentation also noted that "***Unanticipated exclusion of sites due to deviations led to study being underpowered***. Adaptive feature of trial allows the Company to continue enrolling patients to reach statistical significance."

59. On the same day, BioVie hosted a conference call which was led by Defendants Do and Palumbo, as well as the CEO of Pentara Corporation. On the call, Defendant Do noted that the Phase 3 clinical trial "***did not achieve statistical significance because we had to exclude so many patients from the trials that we believe engaged in improper practices***." He further noted that BioVie had to exclude 358 patients, which represented "over 80% of our enrolled populations due to suspected improper conduct at 15 clinical sites," and that "all of these clinical sites had been referred to the FDA."

60. Defendant Do acknowledged that what BioVie found at the affected clinical sites was "so unusual" and explained why BioVie believed it had to exclude the 356 patients. He stated that each site was responsible for uploading data to an electronic database known as the "EDC" for its patients, that the EDC is maintained by the CRO, and that BioVie only had read access to the blinded data. Do noted that the Company "monitors blinded data on an ongoing basis to review safety and ensure that data is entered on a timely basis into the EDC."

61. With regard to six of the clinical sites excluded, Defendant Do stated:

> In parallel, patient facing activities started to wrap up at some of the sites in July of 2023, which provided us the first opportunity to conduct a detailed data review and validation….that is when we started to notice higher than expected levels of deviations….that is when we made the decision to undertake a multi-step review process that involved hiring a supplemental CRO to conduct quality control visits to all sites and then to conduct source data verification or SDV on 100 percent of the materials touched in the clinical sites. Subsequently, a third CRO was hired to audit sites as well. We took this level of proactive actions and diligence that goes way above what is typically done by pharma companies because we understood the importance of this data. We finally received the final QC reports from the supplemental CRO on November 6th, which revealed that six sites that enrolled 128

patients had what appeared to be numerous and significant GCP violations and deviations from our protocol. The deviations were to such an extent that we had to act.

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[W]hen we saw this problem we acted rapidly and vigorously, rather than ignore it because we could not condone the practices we uncovered, such as when multiple patients came in for an MRI scan on the same day they ended up having the same result posted with their records…as a result we did the following: first we updated our statistical analysis plan or SAP to exclude all data from these six deviating sites because the patients and their data were totally suspect. Second, we amended our protocol with the FDA to do two things – first is that we finalize the primary endpoints to be CDR-SB and ADAS-Cog. This was a planned activity as a result of our interaction with the FDA over months…the second thing is that we revised the clinical trial design itself to be an adaptive design so that we may work with the FDA to potentially continue enrolling additional patients if we see an efficacy signal but miss on stats due to the excluded sites. And the third thing we did was referred all six sites to the FDA's Office of Scientific Investigations three days after receiving the CRO's report….on November the 9th.

62. With regard to the other nine sites that were excluded, Defendant Do explained:

When we started unblinding the data, we focused first on the sub-group analyses that Pantera recommended, right, and we found that the anomalous data from the patients from the identified demographic groups could not be explained scientifically. The placebo patients are not expected to significantly and dramatically improve as we saw in the data from this demographic group. The same thing was found regarding the anomalous sites. ***And, in fact, the problem identified with the demographic group and the anomalous sites turned out to be one and of the same in that virtually all patients from the demographic group were associated with the anomalous sites, which were all located in one geographic area***. Thus, we had to exclude these nine sites that enrolled a total of 230 patients as well per our pre-specified SAP. Since virtually all of the now 15 sites suspected of improprieties were in a single geographic area, we suspect that there may be more going on; thus, we referred all 15 sites to the FDA. And since we have a deep respect for the FDA and their investigative processes we are not identifying the geographic area and sites and we have not notified any of the sites as to their status… by excluding 358 patients or over 80% of our enrollment we were left with 81 patients in our modified intent to treat population. This also meant that we only had 57 in the per protocol populations, which are patients who have completed the trial, patients who we can verify have taken the study drug through PK, and so forth.

63. Defendant Do then addressed how such an issue arose:

So the natural question is how could this have happened? That is a great question and I wish I had a simple, great answer for you. But, I believe there are a few confounding factors that got us here. ***First, we started enrolling the trial at the height of the COVID-19 pandemic, where there was limited access to the sites. In fact, the limited access remained the case for most of the duration of the trial. We***

> ***rely on third-parties to execute and monitor the trials so one could say the on the ground oversight of the sights was not what it needed to be.*** Second, we assumed good intent. There are nearly 500,000 clinical sites registered in clinicaltrials.gov, all of whom are licensed. They have to adhere to GCP, and they are periodically audited by the FDA and other agencies. ***We presumed that our clinical sites would act responsibly, but we found ourselves victim of suspected coordinated improprieties at a level that none of us have seen in our careers.*** It's just so unusual. There's just no other way of describing it.

64. During the question-and-answer portion of the call, Defendant Do acknowledged that:

> ***What's very very clear to us here is that monitoring, on-site monitoring of what was going on was not where it needed to be,*** right, and so frankly one of the things we will do is what I have done for my other clinical trials in Asia for example, is we are going to take a belt-and-suspenders approach, right? In those trials I always have my own CRAs alongside the CRO's monitors out at the sites, right, and we are essentially going to go with more established sites that have conducted more of these Alzheimer trials, and frankly we have changed our CRO. And so those are some of the things that we will be doing immediately and we will be working…to identify the other safeguards that we need to put in place – along with the FDA – I think the FDA will have a point of view kind of given the bit of a scandal that we have here with these sites.

65. Another analyst questioned Defendant Do about the "big picture," asking:

> What gives you confidence, excluding these patients, that the data holds, and what would motivate a region, not just one clinical trial site to actually, you know, not run the trial the way it is designed? Like what really happened?

66. Defendant Do responded:

> I don't want to start any conspiracy theories or anything else like that. And it's actually the vast majority or virtually all of 15 sites are in the same geographic area, right, and that is the reason why we have referred this thing on to the FDA to investigate because we would be just speculating, right? ***We do know in certain other disease that there is phenomena [of] professional patients that may be part of what is going on here but I am not going to speculate anything else***.

67. On November 29, 2023, the stock closed at $1.96, down more than 60% from the previous day's closing price of $4.99.

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

PLAINTIFF'S CLASS ACTION ALLEGATIONS

69. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired BioVie securities between August 5, 2021 through November 29, 2023, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

70. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, BioVie's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of BioVie shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by BioVie 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.

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

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

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

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

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

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

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

UNDISCLOSED ADVERSE FACTS

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

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

77. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages

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

LOSS CAUSATION

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

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

SCIENTER ALLEGATIONS

80. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding BioVie, their control over, and/or receipt and/or

modification of BioVie's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning BioVie, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

81. The market for BioVie's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, BioVie's securities traded at artificially inflated prices during the Class Period. On August 5, 2021, the Company's share price closed at a Class Period high of $13.6750 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of BioVie's securities and market information relating to BioVie, and have been damaged thereby.

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

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

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

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

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

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

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

85. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business, operations, compliance, and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might

have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

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

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

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

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

members of the Class to purchase BioVie's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

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

90. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about BioVie's business, operations, compliance, and prospects, as specified herein.

91. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of BioVie's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about BioVie and its business, operations, compliance, and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

92. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors

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

93. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing BioVie's business, operations, compliance, and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, compliance and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

94. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of BioVie's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and

misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired BioVie's securities during the Class Period at artificially high prices and were damaged thereby.

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

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

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

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

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

99. Individual Defendants acted as controlling persons of BioVie within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations

and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

100. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

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

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

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

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

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.