**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| OKLAHOMA FIREFIGHTERS PENSION AND RETIREMENT SYSTEM,<br><br>Plaintiff,<br><br>v.<br><br>BIOGEN INC., MICHAEL VOUNATSOS, MICHAEL MCDONNELL, JEFFREY CAPELLO AND ALFRED SANDROCK,<br><br>Defendants. | Civil Action No. 1:22-cv-10200<br><br>CLASS ACTION<br><br>COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS<br><br>Jury Trial Demanded |

Plaintiff, Oklahoma Firefighters Pension and Retirement System ("Plaintiff"), by and through its attorneys, alleges upon personal knowledge as to itself, and upon information and belief as to all other matters, based on the investigation conducted by and through its attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

## NATURE AND SUMMARY OF THE ACTION

1. This is a securities class action on behalf of all investors who purchased or otherwise acquired Defendant Biogen, Inc, ("Biogen" or "The Company") common stock between June 7, 2021 and January 11, 2022, inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (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.

2. Biogen is multinational biotechnology company headquartered in Cambridge, Massachusetts. Since its founding, the Company has become well known within the biotechnology industry for various proprietary treatments for the treatment of Multiple Sclerosis ("MS") and other chronic conditions.

3. For years, Biogen had made its fortune on innovative treatments for MS – a painful and debilitating chronic condition that for years, had lacked effective treatments. Bringing several different treatments through the Food and Drug Administration ("FDA") approval process to market made Biogen an internationally renowned leader in the biopharmaceutical sector. Yet, by 2019, Biogen was seeing significant competition in markets that it used to dominate. Treatment for MS was no longer lucrative enough to power Biogen's earnings. The Company was searching for another blockbuster drug to replace the revenues it expected to lose from its MS line-up of drugs. That new blockbuster was thought to be Aduhelm, a drug being developed to treat Alzheimer's disease and an experimental mono-clonal antibody therapy for which Biogen conducted two Phase III clinical trials beginning in late 2015.

4. In March, 2019, Biogen announced the interim results of its Phase III clinical trials for Aduhelm based on input from outside advisors Biogen retained to review the data: the result was Aduhelm failed to show sufficient clinical benefit and Biogen determined it would not seek FDA approval for Aduhelm. The outside advisors recommended, and Biogen decided, to abandon Aduhelm as futile.

5. Yet, a group of executives within Biogen did not want to give up. In a series of highly unorthodox maneuvers and meetings, which are now the subjects of investigations by the FDA itself, Congress, the Federal Trade Commission and the Securities and Exchange

Commission, Biogen officials began to meet with Billy Dunn, the FDA's Director of the Office of Neuroscience, in a back door effort to gain FDA approval for Aduhelm.

6. While pharmaceutical companies meet with FDA officials to discuss the make-up of clinical trials and to review and discuss data, Biogen's meeting with Dunn were of a quite different nature. Dunn acted as a de facto advisor and cheerleader to Biogen, explaining how the data could be presented to allow FDA approval for Aduhelm. Dunn told Biogen of five different pathways through which it could get approval.

7. Six months after announcing it was abandoning Aduhelm as futile and that Aduhelm failed to show any clinical benefit, Biogen announced it was submitting Aduhelm for FDA approval.

8. Biogen executives portrayed the data supporting the approval as demonstrating Aduhelm as safe and effective. They omitted to reveal that the data was the exact same data that they determined, just six months earlier, rendered Aduhelm futile and unapprovable. Biogen also failed to reveal their secret, behind the scenes, collaboration with Dunn who shepherded Aduhelm through the FDA approval process despite vehement opposition within the FDA.

9. On June 7, 2021 the FDA approved Aduhelm through its Accelerated Approval process for the treatment of Alzheimer's.

10. Biogen aggressively priced its treatment for Aduhelm at $56,000 a year, as much as 15 times what many analysts were expecting. Defendant Vounatsos stated that Biogen had been engaged with Medicare and third-party payors regarding the price for Aduhelm, suggesting these payers had agreed to provide coverage at that exorbitant price. Sandrock misled investors when he said on June 8, 2021: "For Medicare Fee-For-Service, coverage is automatically presumed with

FDA approval." Given the nature of how Biogen obtained FDA approval, Medicare coverage could not automatically be presumed.

11. While it was one thing to find a cheerleader within the FDA to shepherd the approval for this highly drug, it was quite another to convince third-party payors to pay for it at its exorbitant price.

12. Investors reacted positively to the news that the FDA approved Aduhelm and the price tag assigned to treatment by Biogen. Aduhelm was exactly the blockbuster Biogen had been searching for to replace its MS line-up of drugs. On June 7, 2021, Biogen's stock price skyrocketed by over $100 per share, to close at $395.85 per share, up from its closing price of $286.14 per share on June 6, 2021. Biogen's market capitalization increased by approximately $14.6 billion in a single day.

13. Over the course of the next six months, investors began to learn the truth about Aduhelm and that it would not be the blockbuster drug expected to conquer Alzheimer's and replace the revenues lost from Biogen's MS line-up of drugs. Because Aduhelm was a dangerous and ineffective treatment, hospital networks refused to prescribe it and major insurance companies refused to pay for it. Members of the FDA advisory panel resigned in vocal protest over its approval. Members of Congress demanded an explanation for how Aduhelm was approved. Over the course of months, different parts of the American medical system weighed in, all of them coming to a conclusion at odds with the story Biogen was selling investors. Each event was another small part of showing the public the truth Biogen had tried to hide – Aduhelm would not be Biogen's financial salvation.

14. By the end of October 2021, Biogen began to acknowledge the truth – Aduhelm was not selling well, and its price could not be justified. Aduhelm had generated only $300,000 of revenue in the months since it was approved.

15. By December of 2021 the European Union denied approval of Aduhelm. Japan's drug regulator followed shortly thereafter.

16. Shortly after the EU and Japan refused to approve Aduhelm, the Company announced that it would cut the price of Aduhelm in half. Biogen was still hoping for a favorable decision by Medicare that it would cover the cost of Aduhelm for America's aging population. But that hope would not pay off.

17. On January 11, 2022, the Center for Medicare and Medicaid Services ("CMMS") released its draft opinion, stating it would only pay for Aduhelm for those patients in a hospital sponsored clinical trial. Despite Biogen's previous claims at the transformative nature of the treatment, and touting the FDA's approval and Aduhelm's sales potential, Aduhelm is, essentially, still an experimental drug with a very small market.

18. Biogen's stock price, which skyrocketed to over $395 per share on the news of FDA approval, fell to $225 per share on January 12, 2022 after CMMS released its preliminary determination to not provide coverage for Aduhelm, significantly below the price it traded at before Biogen announced FDA approval for Aduhelm. Biogen's market capitalization declined by almost $25 billion between June 7, 2021 and January 12, 2022 causing investors significant losses.

## JURISDICTION AND VENUE

19. The federal law claims asserted herein arise under §§ 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, as well as under the common law.

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

21. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

22. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b). Biogen is headquartered in this district, and many of the acts charged herein, including the dissemination of materially false and misleading information, occurred in substantial part in this District

23. 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 Nasdaq Stock Exchange ("NASDAQ"), a national securities exchange.

## PARTIES

24. Plaintiff, Oklahoma Firefighters Pension and Retirement System, is the state agency responsible for administering the public pension system for all firefighters in Oklahoma. Created in 1980, it oversees over $260 million of assets, and manages the retirement benefits, disability benefits, surviving spouse benefits, and death benefits.

25. Defendant Biogen, Inc, is incorporated in the State of Delaware and has its headquarters in Cambridge, Massachusetts. The Company's stock trades on the NASDAQ under the ticker symbol "BIIB".

26. Defendant Michael Vounatsos is and was at all relevant times the Chief Executive Officer of Biogen.

27. Defendant Michael McDonnell is and was at all relevant times the Chief Financial Officer of Biogen.

28. Defendant Jeffrey Capello was the Executive Vice President and Chief Financial Officer of Biogen from December 11, 2017 until August 15, 2020. He was CFO until August 15, 2020.

29. Defendant Alfred Sandrock was the Chief Medical Officer of Biogen throughout the class period until December 31, 2021.

30. Collectively, Defendant Vounatsos, McDonnell, Capello and Sandrock, are referred throughout this complaint as the "Individual Defendants."

31. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Additionally, the Individual Defendants were responsible for strategic decisions at the Company that resulted in the allegations being alleged. Because of their positions with the Company and access to material non-public 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 false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

## SUBSTANTIVE ALLEGATIONS

32. Biogen is a global biopharmaceutical company focused on the research, development, and production of therapies for serious neurological and neurodegenerative diseases, and other therapies related to those conditions. It specifically targets treatments for MS, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, and neuropsychiatry. Biogen's current treatment for Alzheimer's disease is Aduhelm, a mono-clonal antibody treatment that purports to reduce the build-up of amyloid plaques in the brain. Reduction of amyloid plaques are believed by some researchers to be a potential avenue for the prevention and treatment of neurological decline from Alzheimer's disease and dementia. Before approval, the drug went by its development name Aducanamab but is referred to throughout this complaint by its current marketing name for ease of reference.

### The Business of Biogen: First Innovation, Then Stagnation, Now Decline

33. The story of Aduhelm is that of a company, Biogen, with sagging sales betting big on a treatment for Alzheimer's to rescue its finances and future sales.

34. Biogen's portfolio of pharmaceuticals is limited, but highly profitable. It has released a number of "blockbuster" drugs that drove its revenues for years. As one large pharmaceutical earner began to fade in sales, Biogen was usually able to bring a new one to market. This began to change right at the time Biogen began its evaluation of Aduhelm's Phase III trials in 2019.

35. To illustrate this, the sales growth and then decrease of two of Biogen's blockbusters: Tecfidera – which eventually became Fumarate – and Spinraza – are discussed in the preceding paragraphs.

36. All numbers come from Biogen's Form 10-Qs and 10-Ks filed with the SEC for the time periods indicated. Biogen reports sales data as year over year changes for a 3-month and 6-month period.

37. In 2015, Aduhelm was little more than a small-scale Phase I trial, and Biogen's earnings were powered by a portfolio of proprietary drugs for MS, most prominently, the drug Tecfidera, approved in 2013 for long term treatment for those with a relapsing form of MS.

38. In the second quarter of 2015, sales of Tecfidera grew year over year growth for a 3- and 6-month period at 14% and 24% respectively. By year end 2015, Tecfidera brought in over $3.6 billion, for a full year growth of 13%, growth driven almost entirely by increases in sales.

39. 2016 was better still. In the second quarter of 2016, sales of Tecfidera grew year over year for a 3- and 6-month period at 39% and 45% respectively. By year end 2016, Tecfidera brought in over $3.9 billion in revenue, another year of growth driven by sales increases.

40. In 2017, Biogen launched its newest blockbuster drug, Spinraza, the first FDA approved treatment for patients suffering from Spinal Muscular Atrophy ("SMA"). It was an immediate success and complimented the continuing impressive earnings from Tecfidera.

41. In the second quarter of 2017, sales of Tecfidera in America had mostly stagnated, revenue increases were due primarily to price increases. Outside the United States, sales continued to grow year over year for a 3- and 6-month period at 25% and 20% respectively, but this was a small fraction of overall Tecfidera sales. Total revenues of the newly released Spinraza started at $241million for the first half of the year.

42. By the end of 2017, Tecfidera brought in $4.2 billion in total revenues, mostly in the United States, but the U.S. market saw a sales decrease of 3% compared to 2016. The revenue gains were primarily driven by price increases for the treatment. This trend of stagnating sales paired with increasing prices to drive revenues would become more prominent for Biogen's MS treatments as time progressed. Spinraza's first year earned Biogen $883 million. Unlike Tecfidera, Biogen was making just as much in the rest of the world from Spinraza as the U.S.

43. In the second quarter of 2018, Tecfidera's sales declines were apparent. In the U.S., sales fell year over year for 3- and 6-month period at 9% and 8% respectively. Outside the U.S., sales were still increasing, but slowly. Year over year for a 3- and 6-month period sales grew at 6% and 14% respectively. Spinraza sales grew year over year for a 3- and 6-month period at 9% and 69% respectively. During this time, Spinraza began to earn more money from the rest of the world than the U.S.

44. By the end of 2018, it was clear Tecfidera's days as Biogen's blockbuster treatment were numbered. Sales were $4.2 billion again, but the U.S market saw a sales decline of 5%, the rest of the world continued to grow at 16%, but still made up less than a quarter of Tecfidera revenues. Spinraza brought in $1.7 billion, with a year over year sales increase of 32%. As Tecfidera was beginning to fade, it seemed possible that Spinraza would be able to fill the hole that was soon to appear in Biogen's earnings.

45. In the second quarter of 2019, U.S. sales of Tecfidera continued to fall year over year for 3- and 6-month period at 0% and 3% respectively. Spinraza's growth continued, but at a more subdued year over year for 3- and 6-month period at 13% and 15% respectively.

46. At the end of 2019, Biogen stopped reporting sales trends for Tecfidera in the U.S., focusing instead on revenues. Tecfidera brought in $4.4 billion, due primarily to price increases.

Most importantly, Biogen noted there were outstanding litigation surrounding the patents related to Tecfidera, and a loss would cause generic competition. For a treatment that was now using price increases to drive revenue growth, this was an existential threat. Biogen was able to bring a complementary treatment to market in October of 2019 called Vumerity that going forward would have its sales reported with Tecfidera as a new treatment package Fumarate. Spinraza, which once could have been hoped to fill the gap, brought in $2 billion and ended the year with a sales increase of 9% compared to 2018. Ominously for Biogen however, competitors had already begun to enter the market, and Biogen noted strong sales thus far were a result of high-level doses to begin treatment which would lower as more patients moved to maintenance doses. Biogen's less prominent products fared no better, in every category revenue stagnated or begun to fall, without other pharmaceuticals to replace them.

47. In the second quarter of 2020, Fumarate sales increased year over year for 3- and 6-month period at 3.4% and 5% respectively. The newly packaged Fumarate had staved off further declines for the time being. Spinraza sales had begun to fall. Its sales fell year over year for 3- and 6-month period at 9.4% and 1.8% respectively.

48. By the end of 2020, Fumarate revenues had begun to fall markedly, bringing in $3.9 billion. The decline was due primarily to generics competition in the U.S. and was projected to further reduce revenues going forward. Spinraza sales had declined precipitously in the U.S., falling 16.8% compared to last year due to a new treatment from a competitor. In the rest of the world Spinraza sales increased 16.8%, but Biogen noted competition was expected in the future.

49. In the second quarter of 2021, Fumarate was becoming an after-thought. Though Biogen was no longer reporting sales trends, it noted revenue in the U.S. had fallen a stunning year over year 70.8% and 70.3% for a 3- and 6-month period. The sales of Fumarate in the rest of the

world, less than a quarter of revenues for the program as little as two years ago, now eclipsed U.S. revenues. According to Biogen the cause was competition from generics in the U.S., with that same competition set to affect the rest of the world in short order. Spinraza sales in the U.S. continued to fall year over year 29% and 33% over 3- and 6-month periods. The rest of the world saw sales increases year over year 17.2% and 14.3% over 3- and 6-month periods. Biogen noted that competition to Spinraza that had gravely impacted U.S. revenues was soon expected worldwide as well.

50. Price increases and a lack of competition prolonged the profitability of Furamate. Spinraza still faced less competition outside of the United States, but Biogen knew as early as 2019 it needed a new blockbuster drug to keep its earnings up, and power its growth. The research and evaluation required for bringing a drug to market is both expensive and time consuming. Biogen decided that Aduhelm was the answer.

**Biogen Bets on Aduhelm**

51. Biogen had been researching Aduhelm in some form or another since 2007, when it licensed the treatment from a Swiss research group, Neurimmue AG. After years of its own research, Biogen began a small Phase I trial to evaluate the treatment's efficacy.

52. The results of that trial were published by Biogen on March 20, 2015. Though the patient group was small, Biogen was so impressed with the results that the decision was made to move directly into two separate Phase III trials, skipping a Phase II study, hoping the data from the Phase III trials would allow for faster approval by the FDA. Biogen referred to the trials internally and to investors as "EMERGE" and "ENGAGE." Patients were enrolled beginning in 2016. Phase III trials are complex and expensive, thousands of patients are required, data gathering is extensive, and the treatment must be produced and evaluated in the condition it would be

administered to patients. Biogen invested considerable resources in running both trials simultaneously.

53. As the Phase III trials continued, Biogen was regularly pressured by investors and analysts for an update on what the data showed, even as the trials were not complete. At the end of 2018, Biogen decided to bring in outside experts to examine the data that had been collected through the end of 2018, and report that data to investors. This analysis took place during the first months of 2019.

54. In March of 2019, Biogen, advised by its independent outside experts, concluded neither ENGAGE nor EMGERGE showed sufficient clinical benefit to submit Aduhelm for FDA approval. The outside advisors recommended, and Biogen decided, to abandon the drug as futile.

55. On March 21, 2019, Biogen announced the results of the Phase III trial, its analysis of the results, and its decision to abandon Aduhelm and cease clinical trials for the treatment. Biogen's stock dropped from $320.59 on March 20, 2019 to $226.88 at market's close on March 21, 2019 it's worst day of trading since 2005. The market's reaction was expected and a disappointment that Aduhelm would not be a blockbuster drug. Defendant Vounatsos noted at the time how the "disappointing news confirms the complexity of treating Alzheimer's disease and the need to further advance knowledge in neuroscience."

56. Unknown to investors, in May of 2019 Defendant Sandrock contacted FDA's Director of the Office of Neuroscience, Billy Dunn, to discuss the data from the Aduhelm trials, and attempt to find a path forward for approval. This meeting was irregular, potentially illegal, and against FDA procedures. It constituted the beginning of Biogen's lobbying campaign of the FDA referred to within Biogen as Project Onyx. The extent and early genesis of the meetings between the FDA and Biogen would be revealed in an investigative report by Stat News on June 29, 2021.

57. On June 14, 2019, Sandrock met with Dunn regarding submission and approval of Aduhelm. At the meeting, Sandrock was assured the FDA would not deem Aduhlem ineffective, and Dunn recommended 5 potential paths to getting Aduhelm through the approval process.

58. From June 15, 2019 through October of 2019, representatives of Biogen and the FDA met regularly to discuss the data, and how Aduhelm could be moved through the approval process.

**Pre-Class Period Misleading Statements**

59. In October 2019, in a complete reversal from its prior disclosures in March 2019, Biogen announced it would seek FDA approval for Aduhelm. In these statements, Biogen omitted to reveal the unorthodox communications and collaboration it had with the FDA and that the prior clinical data determined that Aduhelm provided no clinical benefit. These statements were designed to, and did, mislead investors into believing that Aduhelm would provide an effective treatment for Alzheimers so that, when it was finally approved by the FDA, investors would believe that third-party payors would pay for treatment and the Biogen would have its blockbuster replacement drug.

60. On October 22, 2019, Biogen filed Form 10-Q with the SEC for the 3rd Quarter of Calendar Year 2019 (the "October 2019 10-Q"). The 10-Q was signed by Defendant Capello. In addition to the 10-Q, Biogen issued a separate press release on October 22, 2019, announcing that Aduhelm would be submitted to the FDA for approval and held a conference call with investors.

61. In the October 2019 10-Q Biogen described the decision to submit Aduhlem for approval as:

> "[T]he Phase 3 EMERGE study met its primary endpoint showing a significant reduction in clinical decline. We believe that results from a subset of patients in the Phase 3 ENGAGE study who received sufficient exposure to high dose aducanumab support the findings from EMERGE. The decision to file is based on a new analysis, conducted by

> Biogen in close consultation with the FDA, of a larger dataset from the Phase 3 EMERGE and ENGAGE trials that were discontinued in March 2019 following a futility analysis."

62. This statement was false or misleading when made. It failed to disclose the significant, undisclosed lobbying campaign between Biogen and the FDA that was instrumental in the decision to file and approve Aduhelm based on prior clinical data that previously deemed the drug futile. The term "close consultation with the FDA" does not capture such consultation was outside the processes established by the FDA for communicating data, and a stark deviation from the norms of the FDA approval process. It also claimed the decision to submit for approval was based on a showing of "significant reduction in clinical decline." Later evaluation by outside experts revealed the data merely showed a decline of amyloid plaques, a potential factor in Alzheimer's disease, not a reduction in clinical decline, and certainly not a "significant" reduction. Much of the later controversy regarding Aduhlem's approval stems from its lack of clinical benefit to patients.

63. This statement was material because a reasonable investor reading this statement would conclude Biogen had found an effective treatment for the symptoms of Alzheimer's Disease – neurological decline – rather than a potential way to reduced amyloid plaques. A reasonable investor would further conclude the submission of the treatment for FDA approval was based on sound methodology and statistical analysis, not the end results of a 6-month regulatory lobbying campaign with a friendly FDA administrator.

64. Biogen also held a conference call to discuss the October 2019 10-Q and the submission of Aduhelm. In the conference call, Defendant Vounatsos claimed:

> "First, the decision to stop these trials relied on an earlier and smaller dataset comprised only of patients who had the opportunity to complete 18 months of treatment as of December 26, 2018. At that time, the futility analysis predicted that the trials were unlikely to meet the primary endpoint upon completion. Futility analysis are common in large studies, and they use statistical modeling to attempt to predict the outcome of the studies

based on a number of pre-specified assumptions and criteria. There are multiple methodologies that can be used for futility analysis and the methodology we use was a well accepted approach. However, based on what we have learned, we know now, that the futility analysis did not adequately account for the effect that the earlier enrollment in ENGAGE had on patients overall exposure to high dose aducanumab.

Second, in the months following the discontinuation of the studies, our team has continued to analyze the vast set of clinical imaging and biomarker data that the studies have generated. In addition to further analysis of the data set which informed the futility analysis we also gain access to an analyzed additional data, including data on patients who completed treatment after the cut-off date for the futility analysis as well as data for patients who did not complete the full duration of the study. Once we became aware of the potential implication of this larger dataset, we consulted with external advisors, followed by the FDA with a Type C Meeting in June, as we began conducting further analysis.

Third, the new analysis of the larger dataset which was conducted in consultation with the FDA, showed that aducanumab had a dose-dependent effect on the underlying pathology as measured by amyloid-PET imaging and reduced clinical decline in patients with early Alzheimer's disease as measured by the pre-specified primary and secondary endpoints. Based on the second type C meeting held with the FDA, just yesterday, we believe these data support a regulatory filing"

65. Additionally, on the same earnings call, Sandrock claimed:

"We believe that these positive results for aducanumab represents a turning point for patients, caregivers, physicians and scientists in the fight against Alzheimer's disease. More broadly, we believe these results represent an inflection point in neuroscience drug development and validate our core strategy, by demonstrating the removal of aggregated forms of amyloid beta can result in improved clinical outcomes, we believe these results have positive implications for BAN2401, a distinct antibody that also targets aggregated amyloid beta that we are currently evaluating in a Phase 3 study in early Alzheimer's disease in collaboration with Eisai"

66. The statements made in ¶¶59-65 were false or misleading when made. Biogen had access to all the data used in later evaluations when making the determination in March to abandon Aduhelm. The only change between that decision and the decision to submit Aduhelm for FDA approval was Biogen engaging in an aggressive lobbying campaign with Dunn. Defendants did not disclose to investors the extent of the lobbying Biogen engaged in with the FDA, disclosing only two Type C meetings with FDA staff. In fact, as would be reported by StatNews months later, Biogen was in continual communication with the FDA, a process began during an off-the-books

meeting between Dunn and Sandrock. Communication between the FDA and Biogen would occur daily between the June 14, 2019 meeting and the announcement on October 22, 2019.

67. Defendant Vounatsos's statements were misleading because a reasonable investor would understand from them that the data showing the efficacy of the treatment justified the submission of Aduhelm for approval. A treatment with strong data supporting it would be immensely valuable, but as investors were to learn, Aduhelm's value was all in its advertising from Biogen.

68. Additionally, Biogen's claims that the trials indicated significant clinical benefit were false and misleading when made, all independent examination of the data, and the FDA's flawed approval center on the reduction of amyloid plaques in some cases, not clinical benefit. Sandrock's claims were material because a treatment for Alzheimer's that provides clinical benefit is significantly different, and more valuable, than a treatment that only reduces amyloid plaques and provides limited or no clinical benefit.

69. Biogen's stock ended the day's trading at $281.87, up from a closing price of $223.51 October 21, 2019.

70. On July 22, 2020, Biogen held a conference call with investors to discuss its recently filed Form 10-Q detailing its financial results from the second quarter of 2020. As part of this filing, Biogen announced they had finished submitting Aduhlem to the FDA for approval.

71. On the conference call, Defendant Vounatsos, in describing the submission, claimed:

> "First, we have completed our submission for U.S. approval of aducanumab, an unprecedented opportunity for patients and for Biogen to potentially bring to market the first therapy to reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease. I am incredibly proud of the Biogen team for their dedication and tireless work leading to the completion of our regulatory submission on July 7. This submission followed ongoing collaboration with the FDA and includes data from a

> comprehensive clinical development program, including EMERGE, the first positive Phase III study ever in this space. Together with supporting data from the Phase III ENGAGE study and positive results from the Phase Ib PRIME study, our data show that aducanumab may help to both reduce the decline of cognitive function and help patients' ability to perform certain activities of daily living, which for some patients may result in independence for a longer period of time."

72. Defendant Vounatsos's statement was misleading when made. In describing using "supporting data from the Phase III ENGAGE study" Defendant Vounatsos omitted to disclose that study demonstrated that Aduhelm failed to achieve a clinical benefit to Alzheimer's patients. A reasonable investor would understand from Vounatsos's statements that both studies provided positive clinical data supporting Aduhelm's efficacy. This was not true.

73. Further, Defendant Vounatsos's description of the data as showing that Aduhelm would "reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease" once again misrepresented what the data for Aduhelm actually showed; a reduction in some patients of amyloid plaques. This is significant because a reasonable investor hearing this statement would conclude Aduhelm to be an effective treatment for neurological decline, rather than one that provides a modest benefit in reduction of amyloid plaques. The former is significantly more valuable than the latter and would effect whether third-party payors would pay for Aduhelm treatment.

74. On the same call, Defendant Sandrock, in discussing the submission of Aduhlem to the FDA, claimed:

> "[W]e have completed the BLA submission for aducanumab to the FDA. This submission is based upon EMERGE, the first positive Phase III study for a therapy to reduce clinical decline in Alzheimer's disease; supporting data from ENGAGE, although this study did not meet its primary endpoint; and positive results from the Phase Ib PRIME study."

75. Defendant Sandrock's statement was misleading when made. In describing ENGAGE as "not meet[ing] it's primary endpoint" rather than the truth, Defendant Sandrock

failed to disclose that the ENGAGE was a failed study from which Biogen concluded not to seek FDA approval for Aduhelm in 2019. Defendant Sandrock's omission buttresses and supports Defendant Vounatsos's earlier misleading statement. This statement is also misleading because a reasonable investor would conclude this study supported the efficacy of Aduhelm, rather than it being the same study that a year prior had caused Biogen to conclude submission of Aduhelm was futile as it provided no clinical benefit.

76. On November 6, 2020, a panel of outside medical experts employed by the FDA to advise it on approval of new treatments (the "Advisory Panel") met to consider Aduhelm. By a vote of 10 – 0, with one abstaining, the panel recommended the FDA to not approve Aduhelm based on the lack of proven clinical benefit, and safety risks to patients receiving the treatment. The panel was asked the evaluate the data from the EMERGE Phase III trial – which Biogen claimed showed benefit – without considering the data from ENGAGE – which Biogen admitted failed. Rather than use the ENGAGE study to "support" the EMERGE study as Defendants Vounatsos and Sandrock had claimed in the October 22, 2019 conference call, the FDA specifically directed the advisory panel to ignore the failed ENGAGE study.

77. On April 7, 2021, the FDA's Medical Policy and Program Review Council also voted against recommending approval of Aduhelm.

**Class Period False and Misleading Statements**

78. On June 7, 2021, the FDA approved Aduhelm using the Accelerated Approval process. The Accelerated Approval was justified based on Aduhelm's effects in reducing amyloid plaques in patients, not in preventing cognitive decline. The FDA determined that the reduction of amyloid plaques was an acceptable bio-marker for efficacy of the treatment to justify an Accelerated Approval. Additionally, the FDA approved a broad label for Aduhlem, allowing it to

be prescribed to any patient with Alzheimer's disease. Functionally, this meant the potential patient population for Aduhelm was all individuals with Alzheimer's of any stage in the United States. As part of the Accelerated Approval, Biogen is required to complete a Phase IV study within 9 years to determine the efficacy of Aduhelm.

79. After the approval, Biogen issued a press release regarding the FDA approval and the implications for Biogen. In discussing the results of Biogen's ENGAGE and EMERGE studies, the press release stated:

> "The efficacy of ADUHELM was evaluated in two Phase 3 clinical trials—EMERGE (Study 1) and ENGAGE (Study 2)—in patients with early stages of Alzheimer's disease (mild cognitive impairment and mild dementia) with confirmed presence of amyloid pathology. The effects of ADUHELM were also assessed in the double-blind, randomized, placebo-controlled, dose-ranging Phase 1b study, PRIME (Study 3). In these studies, ADUHELM consistently showed a dose- and time-dependent effect on the lowering of amyloid beta plaques (by 59 percent [$p<0.0001$] in ENGAGE, 71 percent [$p<0.0001$] in EMERGE, and 61 percent [$p<0.0001$] in PRIME)."

80. The statement was misleading when made. In discussing the two Phase III studies, Biogen omitted to disclose that one of the studies was deemed a failure, and that the justification for approval came by disregarding that study. Claiming that the efficacy of Aduhelm "was evaluated in two Phase 3 clinical trials" and then only reporting the reduction of amyloid plaques without the vital context that one of those studies was deemed a failure by Biogen itself provides a misleading picture of the efficacy data.

81. The statements identified in ¶¶78-80 above would cause an investor to understand that all studies done on Aduhelm supported its efficacy and approval. In fact, the failure of the ENGAGE study, and the lackluster results from the EMERGE caused Biogen to conclude in March of 2019 that Aduhelm was a failure and that requesting FDA approval would be futile. Additionally, the ENGAGE study was a key factor in the Advisory Panel's recommendation

against approval at all. The FDA itself recommended ignoring the ENGAGE study in its discussions with Biogen in the summer of 2019.

82. Further, in the same press release, Biogen stated:

> "The ADUHELM safety profile is well characterized in over 3,000 patients who received at least one dose of ADUHELM. The most frequently reported adverse event was radiographic detection of events termed Amyloid Related Imaging Abnormalities, or "ARIA." ARIA (-E and/or -H) was observed in 41 percent of patients treated with ADUHELM 10 mg/kg compared to 10 percent of patients on placebo. Clinical symptoms were present in 24 percent of patients treated with ADUHELM 10 mg/kg who had an observation of ARIA (-E and/or -H), compared to 5 percent of patients on placebo. The most common symptom in patients with ARIA was headache. Other symptoms associated with ARIA included confusion, dizziness, visual disturbances, and nausea. Adverse reactions that were reported in at least 2 percent of patients treated with ADUHELM and at least 2 percent more frequently than in patients on placebo were ARIA-E, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, fall, diarrhea, and confusion/delirium/altered mental status/disorientation."

83. This statement was misleading when made as omitted to disclose the danger to patients was a key factor in both the Advisory Panel recommending against and later international regulators outright denying approval of Aduhelm. Patients being administered Aduhelm require regular brain scans to detect brain swelling and brain bleeds. Further, phrasing the serious side effects as occurring "at least 2 percent more frequently" misled a reasonable investor to believe such side effects were rare. Rather, as later insurance, provider, and international regulators would learn, the side effects were serious enough and common enough to inform questions of whether to approve or prescribe Aduhelm at all. Indeed, a subsequently revealed study showed that 35% of all patients taking Aduhelm experienced brain swelling.

84. Taken together, then statements in ¶¶78-83 misled investors to believe both that all clinical trials of Aduhelm showed strong efficacy of the treatment and that side effects were minor or rare. These misrepresentations further misled investors into believing that hospital networks, insurance companies, and Medicare would pay for coverage for Aduhelm treatment.

85. After the approval, Biogen announced they would be setting the price for a year's treatment of Aduhelm at $56,000 a year. This price as far in excess of Wall Street analyst expectations, which had projected the price at between $10,000 - $25,000. An independent evaluation by the Institute for Clinical and Economic Review ("ICER") conducted shortly before approval found Aduhelm would be cost-effective at between $2,500 - $8,300 due to the limited clinical benefit.

86. After the announcement on June 7, 2021, Defendant Vounatsos, in an interview with CNBC's Power Lunch justified the price:

> "The price is set at $56,000 a year, during the normal year after lengthy engagement obviously this is important with scientific leaders, pharmaco-economists, payers, private and public payers. These are in line with our pricing principle. This is after two decades of having no innovation. This will allow sustainability of continuing to invest in our rich pipeline that goes beyond Alzheimer's, Parkinson's, ALS, stroke, neuropathic pain and many more. So, we believe this is a fair price. We'll be working very closely with Medicare that is covering 80%, we believe approximately of the epidemiology, in order to secure sustainability of the system. And, and monitor very closely, the dramatization. Moreover, we are committed not to take any price increase during the next four years.
>
> …
>
> You know Meg, and we're engaging with Medicare and we're engaging with the private payers since quite a long time. Do you know that today the cost of Alzheimer's is 600 billion to the US in terms of direct and indirect cost. So, it is time without having really a treatment that addresses a defined pathophysiology of the disease, it is really time now that we invest some resources to treatment "

87. The statement in ¶86 was materially misleading. By stating that Biogen was "engaging with Medicare" and "with private payers since quite a long time" Vounatsos is implying that these entities would cover and pay for Aduhelm's treatment, at $56,000 per year. This was false as these entities had not committed to paying for Aduhelm treatment at any price given its questionable efficacy and safety issues, let alone at $56,000 per year. Vounatsos' statement was

further misleading by comparing the cost of Aduhelm to to the total cost of care of Alzheimer's disease suggested that it was an overall cost savings to pay for Aduhelm when, in fact, the drug was not effective in treating Alzheimers and had sever side-effects. Vounatsos also misled investors when he stated that Medicare "is covering 80%" falsely representing that Medicare coverage was a certainty when, in fact, it was not.

88. Stock market analysts expressed surprise at Biogen's pricing for Aduhelm. Brian Abrahams of RBC Capital Markets concluded that "consensus net prices was ~$11.5k and we estimated $12k.9.6k net in U.S" further noting "we believe BIBB may have been best served coming in at a low rather than ultra-premium relative price point …. Ultimately we believe this pricing strategy is likely to generate additional controversy and debate." Piper Sandler's note on the Aduhelm approval modelled net pricing at $20,000 a year." Sumant Kulkarni of Canaccord Genuity Capital Markets modelled Aduhelm at $8,500 a year.

89. Nonetheless, the stock market reacted favorably to the pricing for Aduhelm as Biogen's stock price skyrocketed on June 7, 2021, increasing by over $100 per share on the prospects of the potential revenue from Aduhelm. Biogen's stock ended the day's trading at $395.85 a share, up from the market open of $295.35 and its market capitalization rose by approximately $14.6 billion on June 7, 2021.

90. On June 8, 2021, Biogen held a conference call with investors and analysts regarding the FDA approval of Aduhelm and the company's plans for the drugs. During the call, Sandrock, when discussing the price of Aduhelm, stated:

> "When considering ADUHELM's value proposition, it is important to note that this therapy was studied in early-stage patients. There are several aspects of treatment with ADUHELM that we believe will likely make it a treatment handled mainly by specialists in collaboration with primary care physicians. In determining the price, we engage with

> stakeholders including clinical experts, health economists (00:11:11), policymakers, and payers on ADUHELM, and we remain true to Biogen's pricing principles.
>
> With this consideration in mind, we have priced ADUHELM at WAC of approximately $56,000 per year for an average patient of 74 kilogram at the full maintenance dose. We expect the cost during the first year to be lower due to the dose titration resulting in an average WAC of approximately $41,000 for an average patient.
>
> Importantly, we have committed to not increasing the price of ADUHELM for the next four years. One critical near- term priority for the launch will be securing payer coverage. The vast majority of Alzheimer's patients in the US are 65 or older. And as a result, most of our patients are expected to be covered by Medicare either through fee-for-service or Medicare Advantage. *For Medicare Fee-For-Service, coverage is automatically presumed with FDA approval. We expect most Medicare Advantage Plans to define their medical policies within the first several months after launch.*
>
> …
>
> And we are working to finalize a multiyear agreement with the Veterans Health Administration in order to support access for veterans. ” [Emphasis added.]

91. This statement was misleading when made. First, Sandrock’s statement about “[f]or Medicare Fee-For-Service, coverage is automatically presumed with FDA approval” omits to provide any context or warnings of the very real – and later realized - potential of a negative coverage decision. By misleading investors as to the way in which approval was achieved, that the clinical data did not support a clinical benefit by taking Aduhelm and that side-effects were dangerous and serious, Sandrock and Defendants misled investors as to the likelihood that Medicare would cover Aduhelm.

92. Over the next two days, Biogen’s stock would continue to increase, until it reached its all time high of $414.71 on June 10, 2021.

93. On June 15, 2021, Congressman Peter Welch of Vermont sent a letter to Defendant Vounatsos demanding answers to several questions regarding how Biogen priced Aduhelm. In the letter, Congressman Welch cited the ICER study’s analysis of Aduhelm’s price finding a price of $2,500 - $8,300 would be reasonable, and what the letter claimed was Wall Street analysts top

estimate of $24,000 a year. Congressman Welch's letter noted the cost of Aduhlem was set to eclipse the yearly spending on Medicare Part B by over $20 billion. The letter ended with a demand for justification of the price Biogen set for Aduhelm.

**The Truth Leaks Out**

94. The truth regarding Aduhelm and Biogen's ability to achieve its sales goals and growth for the drug began to slowly leak out over the next 6 months.

95. The first news regarding insurers refusal to provide coverage for Aduhelm emerged on June 23, 2021 when Tufts Health Plan and Harvard Pilgrim Health Care issued a statement saying the price of Aduhelm should be reduced by as much as a factor of 10 for the drug to be covered by the health plan. Biogen's stock price fell from its closing price of $371.90 per share on June 22, 2021 to $349.16 per share on June 23, 2021.

96. On June 29, 2021, StatNews released an exclusive investigate report into the process by which Biogen actively lobbied the FDA for approval of Aduhelm titled "Inside 'Project Onyx': How Biogen used an FDA back channel to win approval of its polarizing Alzheimer's drug".

97. The article detailed a lobbying campaign of the FDA by Biogen that began shortly after the market's strong negative reaction to Biogen's announcement submitting Aduhlem for approval would be futile. Dubbed by Biogen as "Project Onyx" after the first suggested term "Project Phoenix" was deemed inappropriate by Biogen's legal counsel, the program centered on lobbying Dunn and the FDA to disregard the negative clinical data from Biogen's Phase III trials that led to Biogen deeming approval of Aduhelm futile. The reporting dubbed Dunn "an inside ally" and noted "the FDA played an extraordinarily proactive role, even drafting a road map on how the company could win approval." According to the report, the "new analysis" Biogen had

claimed led to filing for approval of Aduhelm was little more than disregarding the negative results of the ENGAGE study. As the results of the Advisory Panel review of Aduhelm shows, the FDA directed the panel to disregard the failed study in their evaluation. The article also claimed the FDA itself recommended Aduhelm be evaluated for approval on its impact on amyloid plaques, rather than clinical impact on neurological decline. This approach, in some cases created by, in other cases validated by the FDA, allowed Biogen to falsely market a failed study and a modest success in reducing amyloid plaques in some patients as "therapy to reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease."

98. On July 9, 2021, the Acting head of the FDA requested an investigation by the U.S. Department of Health and Human Services Inspector General's Office ("HHS IG") into the approval of Aduhelm. Biogen's stock price fell on July 9, 2021 from its prior closing price of $369.05 to close at $358.16 on July 9, 2021.

99. On July 12, 2021, Congresswoman Carolyn Maloney of the U.S. House of Representatives Committee on Oversight and Reform and Congressman Frank Pallone of the U.S. House of Representatives Committee on Energy and Commerce sent a letter requesting documents and records to Defendant Vounastos regarding Aduhlem's efficacy data and the process by which Biogen communicated with the FDA regarding regulatory approval, as part of investigation into Aduhlem's approval. The letter contained numerous allegations of improper communications with regulators, pricing, and questions about Biogen's evaluation of the data used to claim Aduhelm provided a clinical benefit. The letter also cited to the Stat News story of June 29, 2021 and Project Onyx.

100. Also on July 12, 2021 a survey of Blue Cross Blue Shield ("BCBS") plans conducted by Formulary Watch showed that BCBS plans in in North Carolina, Michigan, Western

New York, and Kansas all had refused to cover reimbursement for Aduhelm, deeming the treatment "investigational."

101. Biogen's stock price fell on July 12, 2021 to close at $349.04 per share from its closing price of $358.16 per share on July 9, 2021.

102. On July 15, 2021, the Cleveland Clinic became the first of several medical provider networks to issue a statement saying it would refuse to prescribe Aduhelm due to safety concerns and lack of efficacy.

103. Also on July 15, 2021, Mt. Sinai Health System issued a statement saying it would not provide Aduhelm to patients until the United States Department of Health and Human Service's Inspector General concluded its investigation. Biogen's stock price fell to close at $328.16 per share from its closing price of $352.06 per share on July 14, 2021.

104. On July 22, 2021 Biogen held a conference call to discuss the Company's financial results from the second quarter of 2021. On the call Defendant Vounatsos doubled down on Biogen's misleading representations of the market for Aduhelm and Biogen's pricing of the treatment, stating:

> "We have seen strong indications of very high initial patient interest in ADUHELM as well as increased referrals from PCPs to specialists. However, it will take some time for sites to get up and running. While some large centers have said they will refrain for now from administering ADUHELM to patients, many of the sites are moving forward with internal processes such as pharmacy and therapeutics, or P&T, committee review, with some accelerating faster than we had originally planned. Of the 900 sites approximately which we expected to be ready shortly after approval, we estimate that approximately 325 or 35% have completed a P&T review with a positive outcome or indicated that they won't require a P&T review.
>
> We have also seen some sites leverage external infusion centers in the face internal resistance or are waiting clarity on their facilities internal process. We continue to believe that consistent with our clinical trials, more specialists will require confirmation of amyloid beta pathology, either via PET or CSF, which is also taking time to schedule and coordinate.

> In terms of reimbursement, it is still the early days. And I am pleased to say that we have seen the first examples of Medicare Advantage plans approving pre-authorization. We welcome the recent opening of the National Coverage Determination analysis by CMS for monoclonal antibodies targeting amyloid-beta, including ADUHELM. We believe this process will provide additional clarity on coverage for Medicare beneficiaries and drive consistency of access across the country. We expect that regional Medicare Administrative Contractors and Medicare Advantage plans will provide coverage for ADUHELM while the NCD analysis is underway. We believe that CMS's swift decision to initiate the NCD analysis is a testament to the large unmet need in Alzheimer's disease and the urgency to clarify access for patients."

105. Defendant McDonnell furthered the misleading impression to investors, when on the same call, in response to a question from Cory Kasimov of JP Morgan, stated:

> "And just to quickly add to that, where we have 35% that have completed a P&T review with a positive outcome or indicated they won't require, you should not assume that the remaining 65% have come back negative. It's very early days, and the majority of those are still outstanding"

106. The statements in ¶¶104-105 were misleading when made. Discussing demand for Aduhelm in terms of referrals to specialists would make a reasonable investor believe this metric is the key to whether or not more Aduhelm would be prescribed or sold. Instead, it is insurers and providers that are the key to a treatment's success. In the case of Aduhelm, the exorbitant pricing for the treatment, paired with continuing concerns over efficacy meant providers were refusing to prescribe the treatment, and insurers were refusing to pay. Further, referencing that 35% of Biogen's projected treatment sites have agreed to provide Aduhelm, paired with statements indicating it was still early and more approvals would potentially follow misrepresented the trends Defendants Vounatsos and McDonnell were both aware of. The conference call came only a week after several prominent provider networks indicated they would not prescribe Aduhelm. Defendants Voutnatsos and McDonnell's statements would cause a reasonable investor to think these were exceptions, rather than, as later corrective disclosures reveal, reflective of broader prescription and reimbursement trends.

107. In response to these statements, Biogen's stock price increased on July 22, 2021 to close at $326.36 per share, up from its prior close of $322.96 per share.

108. On August 8, 2021, the HHS IG's office announced a broad investigation into the FDA's Accelerated Approval process as a result of the Biogen approval.

109. On August 11, 2021 the U.S. Department of Veteran's Affairs ("VA") announced that it would not add Aduhelm to its formulary list citing "a lack of evidence of a robust and meaningful clinical benefit and the known safety signal." While it is possible for veterans who received VA health care to receive treatments not on the formulary list, the process is detailed and individualized. This decision functionally closed off most veterans as potential patients for Aduhelm. As detailed in ¶90 Biogen had deemed negotiations over an agreement with the VA in its final stages.

110. On October 20, 2021, Biogen held a conference call to discuss its financial results in the 3rd Quarter of 2021 with investors. In the call, Defendant Vounatsos partially admitted the truth about Aduhelm's efficacy as a treatment, while at other points continuing to make false or misleading statements. In the call, Defendant Vounatsos said:

> "We are working through the three near-term challenges we have previously described with a core focus on enabling patients access. Importantly, we have made steady progress on key metrics. But the healthcare system remains a major bottleneck. In particular, the lack of clarity on reimbursement has delayed patient access to the first treatment to address an underlying pathology of Alzheimer's disease which is reasonably likely to predict clinical benefit. We look forward to the upcoming Medicare National Coverage Determination expected by next April which would clarify Medicare reimbursement for the entire class of antibodies directed against amyloids. The NCD is a rigorous process involving a number of consultation and we understand this is required for this new class of drugs for Alzheimer's. However, keep in mind, this will delay access for many patients by approximately 300 days from approval.
>
> Biogen is acting with urgency across the three strategic priorities as we work to support access for patients. First, we are working to improve the community's understanding of our clinical data. As a reminder, the Phase 3 EMERGE study met its pre-specified primary and secondary endpoints showing a significant reduction in clinical decline. Patients who

> received high dose ADUHELM experienced significant benefits on measure of cognition and function, including activities of daily living. Although the other Phase 3 study ENGAGE did not meet its primary endpoint analysis, both studies demonstrated that higher exposure to ADUHELM were associated with greater reduction in clinical decline. We have submitted this Phase 3 results to a top tier journal with a manuscript now under peer review in addition to all the publication on our data and we will continue to generate additional data."

111. In contrast to statements made when Aduhelm was first approved on June 7, such that it was "the first therapy to reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease" Defendant Vounatsos now described Aduhelm as "the first treatment to address an underlying pathology of Alzheimer's disease which is reasonably likely to predict clinical benefit." This is a far more accurate description of Aduhelm and its benefits.

112. However, Defendant Vounatsos' statement that "a lack of clarity on reimbursement has delayed patient access" was misleading. As was reported at the time and had been true for months, private insurance carriers were denying reimbursement due to Aduhelm's exorbitant cost and providers were refusing to prescribe it due to its lack of clinical benefit.

113. As part of the announcement of Biogen's 2021Q-3 financial results, Biogen disclosed sales of Aduhelm totaled only $300,000.

114. On November 15, 2021 after the close of the markets, StatInc. reported that Sandrock was resigning from Biogen due to the unusual way in which the FDA approved Aduhelm. Biogen's stock price fell on November 16, 2021 to close at $261.55 per share from its prior closing price of $271.82 per share.

115. On November 17, 2021 Biogen announced the European Union was unlikely to approve Aduhelm.

116. On November 23, 2021 reports emerged that a new study showed that 35% of patients taking Aduhelm experienced brain swelling. Biogen's stock price closed at $250.13 per share down from its closing price of $254.15 per share on November 22, 2021.

117. On November 26, 2021 Bloomberg Business news reported that Biogen's stock price had given up all its gains from its initial announcement of FDA approval for Aduhelm, citing rejection of the drug by European regulators and new safety data demonstrating that 35% of patients experienced brain swelling when on the drug. By December 1, 2021 Biogen's stock price declined to close at $229.50 per share.

118. On December 20, 2021, the European Union's Committee for the Medicinal Products for Human Use (the "CHMP") officially rejected Aduhelm for approval in the European union. In rejecting Aduhelm, the CHMP stated:

> "[A]lthough Aduhelm reduces amyloid beta in the brain, the link between this effect and clinical improvement have not been established… results from the main studies were conflicting and did not show overall that Aduhelm was effective at treating adults with early stage Alzheimer's disease.
>
> In addition, the studies did not show that the medicine was sufficiently safe, as images from brain scans of some patients showed abnormalities suggestive of swelling or bleeding, which could potentially cause harm. Furthermore, it is not clear that the abnormalities can be properly monitored and managed in clinical practice.
>
> Therefore, the agency's opinion was that the benefits of Aduhelm did not outweigh its risks."

119. The evaluation of the CHMP mirrors that of the Advisory Committee members who voted not to recommend Aduhelm for approval. They also directly contradict the repeated characterization of Aduhelm's efficacy by Biogen and the Individual Defendants.

120. Also on December 20, 2021, Biogen announced it was cutting the price of Aduhelm in half, to $28,200.

121. On December 22, 2021, Biogen announced Japan was also unlikely to approve Aduhelm. With the rejection of both the EU and Japanese drug regulators, Biogen would be completely reliant on sales of Aduhelm in the United States. With many providers refusing to prescribe the treatment, and many insurance carriers refusing to provide reimbursement for it, the decision by the U.S. Center for Medicare and Medicaid Services ("USCMMS") would be vital.

122. On January 11, 2021, after the close of stock trading, CMMS announced their draft decision on reimbursement for Aduhelm. CMMS proposed to cover reimbursement under "Coverage with Evidence Development," limiting reimbursement only to patients enrolled in a clinical trial. Additionally, it limited those patients eligible as those with mild forms of cognitive impairment or mild dementia and those who patients who already have amyloid plaques. Further, CMMS proposed limiting reimbursement to clinical trials in a hospital-based outpatient setting. The restrictions on reimbursement target a small patient population, and with many hospitals refusing to provide Aduhelm at all, where those clinical trials could take place is limited. Private insurance providers often follow the guidance of CMMS in their own coverage decisions. Functionally, USCMMS has agreed to reimburse Biogen for running a new clinical trial, all but destroying the value of Aduhelm as an approved drug.

123. Biogen's stock price plunged on the news, closing at $225.34 per share, down from its closing price of $241.52 per share on January 11, 2022.

124. The events detailed in ¶¶94-123, each serve as partial corrective disclosures to Biogen's false or misleading statements. All provide the market information to correct the false misrepresentations that Aduhelm would be a significant earnings driver for the Company.

125. As was known by Biogen as early as March of 2019, Biogen had not demonstrated clinical benefits to patients, the side effects were significant, and those who could potentially benefit from the treatment were limited to those with mild or early Alzheimer's.

**CLASS ACTION ALLEGATIONS**

126. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired the Company's common stock between June 7, 2021 and January 11, 2022, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

127. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Biogen has more than 146 million shares of its common stock outstanding which trade on the NASDAQ stock exchange.

128. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

129. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

130. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

131. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**FRAUD ON THE MARKET**

132. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things;

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock, and;

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

133. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

**NO SAFE HARBOR**

134. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

135. To the extent there were any forward-looking statements, 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.

**LOSS CAUSATION**

136. During the Class Period, the price of Biogen's common stock declined as the stock market learned that Biogen obtained FDA approval through questionable and unorthodox methods, that various investigations were being launched into the approval, that providers were generally not prescribing Aduhelm and that hospitals, insurers and Medicare would not pay for its treatment coverage. As this news leaked out, Biogen's stock fell from a high of $414.71 per share to $225.34 per share.

**Count I**
**Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder**
**(Against All Defendants)**

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

138. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were 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.

139. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (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 those who purchased or otherwise acquired the Company's securities during the Class Period.

140. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

**Count II**
**Violation of § 20(a) of the Exchange Act**
**(Against the Individual Defendants)**

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

142. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the documents were false or misleading statements were made and other statements alleged by Plaintiffs to be false or misleading both prior to and immediately after their publication and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

**PRAYER FOR RELIEF**

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

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive 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 pre-judgment and post-judgment interest thereon;

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff here demands a trial by jury in this action of all issues so triable.

February 7, 2022

Respectfully submitted,

/s/ Jeffrey C. Block
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