

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

OKLAHOMA FIREFIGHTERS PENSION
AND RETIREMENT SYSTEM,

Plaintiff,

v.

BIOGEN INC., MICHEL VOUNATSOS,
AND ALISHA ALAIMO,

Defendants.

Civil Action No. 1:22-cv-10200-WGY

~~[PROPOSED]~~ REVISED THIRD
AMENDED ACTION COMPLAINT FOR
VIOLATION OF THE FEDERAL
SECURITIES LAWS

Leave to file granted Feb. 11, 2026 per the
Court's order granting, in part, Plaintiff's
Renewed Motion to Amend

Jury Trial Demanded

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1. Lead Plaintiff, Oklahoma Firefighters Pension and Retirement System (“Lead Plaintiff”), alleges the following based upon (1) the investigation undertaken by Lead Counsel—which included, but was not limited to, the review and analysis of (i) public filings made by Biogen, Inc. (“Biogen” or the “Company”) with the U.S. Securities and Exchange Commission (the “SEC”); (ii) press releases and other public statements issued by Defendants; (iii) research reports issued by securities and financial analysts; (iv) media and news reports and other publicly available information about Biogen and Defendants; (v) a Congressional Report titled “The High Price of Aduhelm’s Approval: An Investigation into FDA’s Atypical Review Process and Biogen’s Aggressive Launch Plans;” (vi) transcripts of Biogen’s earnings and other conference calls with investors and analysts; (vii) publicly available presentations, press releases, and interviews by Biogen and its employees; (viii) economic analyses of the movement and pricing of Biogen’s publicly traded common stock; and (2) documents produced by Defendants in the course of discovery and deposition testimony.

2. Lead Counsel’s investigation into the factual allegations continues, and many of the relevant facts are known only to Defendants or are exclusively within their custody or control. Lead Plaintiff has now obtained substantial document production from Defendants and numerous third parties, including the U.S. Food and Drug Administration (“FDA”) and the U.S. Centers For Medicare and Medicaid Services (“CMS”).

3. This is a securities class action brought against Biogen and two of its executives (collectively “Defendants”) for false and misleading statements made to investors in connection

with the Company's rollout of aducanumab, branded as Aduhelm¹, a monoclonal antibody treatment for Alzheimer's disease. The class is comprised of investors who purchased or otherwise acquired Biogen stock between June 7, 2021, and September 8, 2021, inclusive (the "Class Period"). Defendants false and misleading statements made in connection with the rollout of Aduhelm violated 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.

4. Defendants misled investors as to the commercial readiness for Biogen's new drug, Aduhelm through three categories of false and misleading statements, and omissions of material facts necessary to make the statements they did make not misleading: (i) statements that Medicare coverage of Aduhelm was "automatically presumed" with FDA approval; (ii) statements that Biogen had engaged and consulted with payers on the price for Aduhelm; and (3) statements that regional Medicare Administrative Contractors (MACs) and Medicare Advantage plans, "will provide coverage" for Aduhelm during the pendency of a national coverage analysis announced by the U.S. Centers for Medicare and Medicaid Services ("CMS"). Defendants' false and misleading statements, and omissions of material facts, inflated and maintained inflation in the Company's stock price.

5. By the end of the Class Period, Biogen's stock price fell in reaction to revelations that: (1) Medicare coverage for Aduhelm was not automatically presumed; (2) Biogen had not engaged or consulted with payers regarding Aduhelm's annual \$56,000 price; and (3) MACs,

¹ For ease of reference, this complaint uses Aduhelm throughout, though prior to FDA approval both internal and public documents referring to the treatment routinely refer to the compound's unbranded name, Aducanumab.

Medicare Advantage plans, and commercial payers were not covering Aduhelm during the pendency of the national coverage decision (“NCD”) analysis due to reimbursement uncertainty and (4) Medicare would only cover patients enrolled in approved clinical trials. As discussed in Section IV. K. (Loss Causation) Biogen’s stock price declined when information came into the stock market, eliminating the artificial inflation in Biogen’s stock price and causing investors to suffer losses.

I. INTRODUCTION

6. Biogen is multinational biotechnology company headquartered in Cambridge, Massachusetts. Since its founding in 1978, the Company has become well known within the biotechnology industry for its focus on the research and development of treatments for multiple sclerosis, Alzheimer’s disease and other chronic neurological diseases and conditions.

7. Biogen’s work developing Aduhelm dates to at least 2007. In 2015, the Company announced positive results from a Phase I trial of the treatment. The prospect of developing and bringing to market the first FDA approved treatment for Alzheimer’s disease had potentially immense implications for the Company as well as the millions of people suffering from the disease and those caring for them. Biogen moved aggressively to pursue this opportunity. In August 2015, Biogen began two simultaneous Phase III efficacy trials for Aduhelm.

8. By 2019, Biogen faced declining sales, increasing competition, or both, for a range of its other products, and it became increasingly clear both within the Company and to investors that the financial trajectory of the Company was intertwined with, if not dependent on, Aduhelm’s prospects for regulatory approval and commercialization. There was immense pressure on the Company and its executives to ensure that Aduhelm proved to be both a clinical and commercial success. Indeed, on the day Biogen announced the FDA approved Aduhelm, June 7, 2021, stock

market analyst Steven Seedhouse, of Raymond James & Associates, wrote that Aduhelm “may have saved the company actually given the myriad franchise and competitive risk throughout the rest of their commercial businesses”

9. Prior to the start of the Class Period, Defendants began to tell investors that Biogen would be ready to immediately begin commercial sales of Aduhelm after its approval by the FDA. For example, on an earnings conference call on February 3, 2020, Defendant Michel Vounatsos said that Biogen was “ready to launch [Aduhelm] in the U.S., if and when it is approved. . . . We believe there are several hundred sites in the U.S. that are ready to start treating patients should [Aduhelm] be approved.” On the same call, in discussing the price for Aduhelm, Vounatsos said “we are getting there. We had very large engagements with many stakeholders.” On an April 22, 2021 earnings call Vounatsos said that “[w]e anticipate approximately 600 ready-to-treat [Aduhelm sites], but many more in the works.” And, he said, in response to an analyst’s question, that “[c]oncerning price, I think that we are there, Mike. We have done a thorough engagement with different stakeholders, considering the burden of the disease and the clinical meaningfulness that [Aduhelm] will bring.”

10. Defendants Michel Vounatsos and Alisha Alaimo made materially false and misleading statements to investors regarding Aduhelm’s commercial viability. First, they misrepresented that upon FDA approval of Aduhelm, “Medicare fee-for-service, coverage is automatically presumed.” Second, Vounatsos misrepresented that Biogen had engaged and consulted with payers “in determining” Aduhelm’s price; and Third, they misrepresented that Regional MACs and Medicare Advantage plans “will provide coverage” of Aduhelm during the pendency of the NCD.

11. On June 24, 2021, Biogen's stock price fell from its June 23, 2021, closing price of \$371.90 per share to close at \$349.16 per share. This decline came after Biogen issued a press release on June 23, 2021, stating it was ready to address "the price of ADUHELM, impact on healthcare budget and patient access." Biogen committed to "stand[ing] ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments shares or out-of-pocket expenses for patients treated with ADUHELM." *Bloomberg Business News* reported on Biogen's press release in an article entitled, "Biogen Expects Slow Alzheimer's Drug Uptake, May Reset Price." Later that same day, after market close, Senators Elizabeth Warren and Bill Cassidy published a letter to Senators Ron Wyden and Mike Crapo, members of the Committee on Finance, regarding CMS's treatment of Aduhelm. The letter stated that CMS could restrict coverage for Aduhelm and specifically noted that FDA approval did not mean Aduhelm was automatically covered by Medicare. Also on June 23, 2024, after market close, the *Boston Globe* published an article stating that CMS could move to "establish nationwide standards" for Aduhelm through an NCD.

12. On July 12, 2021, CMS announced it would undertake a National Coverage Analysis of monoclonal antibody treatments—including Aduhelm—which would result in an NCD.

13. On July 15, 2021, Biogen's stock fell by \$23.90 per share to close at \$328.16 per share. On this day, UnitedHealth Group, a large MAC, stated it would wait for a decision on the NCD before deciding whether to provide coverage for Aduhelm. The same day, Dr. Mark McLellan, a former CMS administrator, FDA commissioner, and consulting expert to Biogen regarding Aduhelm, publicly stated that he believed MACs and MA plans would not cover Aduhelm until after CMS issued its NCD.

14. On July 22, 2021, during Biogen’s Q2 2021 earnings conference call, both Vounatsos and Alaimo informed investors that they expected MACs and MA plans “will provide coverage” of Aduhelm during the pendency of the NCD.

15. On September 9, 2021, Vounatsos and Alaimo attended a Morgan Stanley Healthcare conference. Vounatsos said the Aduhelm launch had been “slower than we initially anticipated” and Alaimo said that a “main challenge[] ... contributing to this gradual launch” was the “higher-than-expected level of uncertainty with respect to reimbursement... compounded by the [NCD] analysis by CMS.” Alaimo continued: “[w]e believe the majority of sites are waiting for clarity on reimbursement, including the outcome of the NCD.”

16. Biogen’s stock price fell 6.7%, from \$321.55 to \$300.15 on September 9, 2021.

17. As discussed in more detail herein, Vounatsos and Alaimo either knew, or recklessly disregarded, that their statements were materially false and misleading, and omitted to reveal material facts, when they were made.

18. First, Vounatsos and Alaimo knew, or recklessly disregarded, that Medicare coverage was not automatically presumed with FDA approval. They were specifically informed that if the FDA approved Aduhelm with a broad label—which it did—MACs and MA plans would push CMS to undertake an NCD. Limited coverage was a likely outcome in this scenario. They were also informed both that CMS would likely scrutinize a drug that had a large budgetary impact, and that Biogen anticipated Aduhelm would be Medicare’s single largest budgetary item within two years. They were thus informed that the factors making an NCD likely were met and that this process would likely impose coverage restrictions. Not only was coverage not “automatic,” but coverage would likely be limited.

19. Second, Vounatsos and Guindo both testified that Biogen did not discuss Aduhelm’s price with anyone outside of Biogen prior to the FDA approving the drug. They knew, or recklessly disregarded, that it was false and misleading to say that Biogen had engaged and consulted with payers “in determining” Aduhelm’s price when, in truth, they never engaged or consulted with any payer on Aduhelm’s price. Instead, Biogen proposed that Aduhelm’s overall value to society—reducing the overall costs to society for caring for Alzheimer’s patients—would justify Aduhelm’s price. Yet, Vounatsos and Guindo knew CMS would consider Aduhelm’s budgetary impact, and not the costs to society of Alzheimer’s’ disease in assessing whether Medicare would provide coverage for Aduhelm.

20. Lastly, both Vounatsos and Alaimo were informed by a team of senior Biogen personnel that, if Aduhelm was approved with a broad label, MACs and MA plans would push CMS for an NCD and would slow and resist coverage until after CMS issued the NCD. They therefore knew, or recklessly disregarded, that MACs and MA plans would set up “immediate barrier[s]” to payment until after the NCD was decided and would not “provide coverage” while the NCD was pending.

21. As the truth emerged on June 24, July 15, and September 8, 2021, Biogen’s stock price declined as the artificial inflation was removed as set forth in Section IV. K. herein.

II. JURISDICTION AND VENUE

22. The 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.

23. 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 and 28 U.S.C. § 1331.

24. In connection with the acts and conduct 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 Market, a national securities exchange. In connection with the acts and omissions at issue in this action, this Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation with 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.

25. Venue is proper in this judicial district pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b). Biogen maintains its corporate headquarters in this district, and did so at all relevant times, and many of the acts and conduct that constitute the violation of law complained of herein, including dissemination to the public of materially false or misleading information, occurred in and/or were issued from this District.

III. PARTIES

26. Lead 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 \$3.52 billion of assets, as of June 30, 2021, and manages the retirement benefits, disability benefits, surviving spouse benefits, and death benefits.

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

28. Defendant Michel Vounatsos was at all relevant times the Chief Executive Officer of Biogen.

29. Defendant Alisha Alaimo is and was at all relevant times the President of Biogen U.S.

30. Collectively, Defendant Vounatsos and Alaimo, 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. Each of 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 all allegations. 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.

IV. SUBSTANTIVE ALLEGATIONS

32. Biogen is a global biopharmaceutical company focused on the research, development, production, and sale of pharmaceutical treatments for serious neurological and neurodegenerative diseases. Biogen’s work developing Aduhelm dates to at least 2007. Aduhelm is a monoclonal antibody treatment that purports to reduce the build-up of amyloid beta in the brain. Amyloid beta is correlated with Alzheimer’s disease and some research suggests that

reduction of amyloid beta could be an avenue for prevention and treatment of neurological decline from Alzheimer's disease and dementia.

A. Biogen's Aging Line of Products and Need for a Blockbuster Replacement

33. Since its founding, Biogen focused on treatments for medical conditions that are complex, debilitating and largely lacked effective treatments. Initially, this involved focus on Multiple Sclerosis, where Biogen was successful in creating several "blockbuster" – expensive, but effective treatments which became the benchmark for the treatment of the disease – treatments. It has repeated this successful approach with treatments for spinal muscular atrophy. As a result, the treatments Biogen sells are limited in number, but each is highly profitable. It has managed to release a number of blockbuster drugs that drove revenue for years. As one large earner began to fade in sales, Biogen was usually able to bring a new one to market.

34. For years, Biogen's blockbuster treatment for MS was Tecfidera, a proprietary treatment that allowed Biogen to dominate the market for this painful chronic condition. Biogen's SEC filings throughout 2017 show that Tecfidera sales as the main driver of earnings, and management comments regularly touted this treatment as a key earnings driver.

35. Analysts and management began expressing concern about future potential for Biogen's MS treatments towards the end of 2017, as market share growth was falling in Japan, and competition from Roche's competing treatment Ocrevus became a factor. Additionally, though 2017 saw the launch of Spinraza, Biogen's proprietary treatment for Spinal Muscular Atrophy Valens research analysis of 2017 year-end earnings pointed towards competition in MS, and potential inability to expand global availability of Spinraza as potential sources of concern for Biogen.

36. David Toung of Argus Research noted as early as February 16, 2018, that “the company’s MS drugs are facing heightened competition from Roche’s Ocrevus, which was launched in the US in 2Q17 and was approved in Europe in January of 2018. They are also likely to face additional competition from Mylan’s generic version of Copaxone later this year and from Celgene’s Ozanimod in 2019.” Additionally, when he looked at Biogen’s newest drug, Spinraza, Tuong noted there was already trouble. “Even Spinraza, which has seen strong initial growth, may face competition in 2019 as Avexis works to develop a rival gene therapy treatment for spinal muscular atrophy.” Argus also noted that “the main drivers of 4Q revenue growth were Tecfidera (\$1.076 billion; +7%), Spinraza (\$363 million; +778%) and biosimilars (\$122 million; +130%).” In Biogen’s product line, there was Tecfidera, there was Spinraza, and then there was everything else. Analysts saw both as facing troubles over the next year. These predictions would prove prescient. By August 23, 2018, Toung noted that Spinraza sales growth was already slowing in the United States, while Biogen’s MS portfolio led by Tecfidera saw revenues fall 2%.

37. At the same time that MS sales were slowing and Spinraza was only partially filling the gap, Biogen was conducting Phase III trials into the treatment that would become Aduhelm. The trials began enrollment in 2017, and Biogen announced it would conduct a futility analysis in the beginning of 2019. A futility analysis is a process where a company will bring in a team of outside experts to examine what results are available and determine if a trial is showing sufficient progress to justify continuing. If not, a treatment is deemed “futile” to submit to the FDA for approval and abandoned. Futility analyses are common for treatments that are examined over long-time frames, or have a large expense associated with the study. Aduhelm was both.

38. On March 21, 2019, Biogen announced the results of its futility analysis, stating that the outside experts it had retained to evaluate Aduhelm concluded submitting it for FDA

approval would be futile. The news was met with despair by investors and analysts, many of whom had seen Aduhelm as the future of Biogen, and the only plausible path towards continued growth. The day of the news, Yatin Suneja of Guggenheim Securities released an analyst report titled “Investors’ Worst Fears Come True; Aducanumab Trials Discontinued; IP Risk Around Tecfidera Next Overhang” where the analyst predicted a 15 – 20% price decrease for Biogen stock based just on this news. Many analysts and firms downgraded their recommendations about Biogen, and even those who were otherwise optimistic deemed Biogen at a “strategic crossroads” like Sumant Kulkarni of Cannacord Genuity, who dropped the firm’s price target from \$396 to \$275 a share based entirely on the failed study. Guggenheim went further, dropping their price target to \$236 a share, and noted Biogen faced significant challenges on:

MS franchise durability, mainly around Tecfidera IPR, (2) Spinraza L-T growth sustainability in the face of competition, and (3) mgmt’s ability to aggressively deploy \$24B in balance sheet capacity towards potential M&A.

39. Without the possibility of Aduhelm to support Biogen’s long-term growth, many analysts began looking far more skeptically at Biogen’s long-term prospects. Argus Research noted in their analyst note on May 6, 2019, that MS treatments now made up 60% of Biogen’s revenue, and Spinraza, then the only Spinal Muscular Atrophy treatment on the market, had two competitors with treatments about to receive a decision from the FDA.

40. In October of 2019, Biogen announced that based on a new analysis of the Phase III data on Aduhelm, it would pursue approval from the FDA.

41. By the end of the 2019, Biogen’s SEC filings show that growth of Tecfidera revenues was primarily due to price increases and not sales growth. Additionally, Tecfidera was subject to litigation surrounding its patents. While Biogen received approval for a complimentary treatment, Vumerity, which it would begin reporting revenues to investors together with Tecfidera

as Fumarate, its MS portfolio growth had stagnated. While Spinraza revenues continued to grow, sales increased only 8% over all compared to the previous year. More ominously, competitors were entering the market for spinal muscular atrophy, and Biogen noted in its filings that its strong sales numbers were driven in part by the fact that new patients receive a larger dose than those currently enrolled. Without new a steady stream of new patients, sales and revenues would fall. Finally, sales of Biogen's less prominent products were similarly either beginning to stagnate or fade.

42. By the end of 2020, Biogen's SEC filings showed that Fumarate – the combined Tecfidera and Vumerity product listing – had begun to fall due primarily to generic competition. Spinraza sales had fallen in the U.S. 16.8% from the previous year. In evaluating earnings from the last quarter of 2020, Yatin Suneja summed up Biogen's status pithily in the title of his report “In-line 4Q2020; Below Consensus 2021 Guide, But Hey, It's All About Aducanumab!” Suneja kept his evaluation of Biogen as a buy with the following rationale: “[w]e believe aducanamab remains the key focus for investors and with the recent extension of the PDUFA date to 6/7/2021, we are more confident on approval.” Despite flagging sales of previous blockbuster treatments, investors and analysts saw Aduhelm as the solution.

43. So did Biogen's executive leadership. In a presentation to the Board of Directors in September 2020, Alisha Alaimo, Deb Glasser, and other Biogen senior executives emphasized that “[o]ur ambition is to make history” and “establish ADUHELM as one of the top pharmaceutical launches of all time.” The presentation highlighted the goal of making Aduhelm a “blockbuster” drug within 12 months of launch and modeled that Biogen's revenue from Aduhelm would reach roughly \$8.4 billion by 2024. A second September 2020 Board presentation from an executive, who was at the time leading Biogen's global product strategy, proclaimed that the company would deliver a “transformative launch of aducanamab.” A third September 2020 Board presentation predicted that, while Biogen was facing some financial headwinds, “our top and bottom line will

quickly rebound with the launch of aducanumab” and that Aduhelm was “potentially a \$18B peak revenue product.”

B. The Development, Failure, and Resurrection of Aduhelm

44. Biogen first licensed Aduhelm from Neuroimmune AG, a Swiss biopharmaceutical company, beginning in 2007. After years of its own research, Biogen began a small Phase I trial to evaluate the treatment’s efficacy.

45. Biogen published the results on March 20, 2015. Though the patient group was small, Biogen leadership was so impressed with the results that the Company moved quickly into two separate Phase III trials, hoping the data from two Phase III trials would provide more data so as to allow for faster approval by the FDA. Biogen referred to the trials 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. The purpose of a Phase III trial is to demonstrate that a drug, therapy, or treatment is both safe and effective in the form that will be administered to patients. Biogen invested considerable resources in running both trials simultaneously.

46. As the Phase III trials progressed, Biogen was regularly pressured by investors and analysts for updates on what the data showed, even as the trials were not complete. At the end of 2019, Biogen decided to bring in outside experts to examine the data that had been collected through the end of 2019, and report that data to investors. For longer term Phase III trials, such a futility analysis is common practice. This analysis took place during the first months of 2019.

47. After a few months of review, in March of 2019, Biogen, advised by its independent outside experts, concluded neither ENGAGE nor EMERGE showed sufficient clinical benefit to

submit Aduhelm for FDA approval. The outside advisors recommended, and Biogen decided, that submission of the treatment would be futile, and the treatment be abandoned.

48. On March 21, 2019, Biogen announced the results of the futility analysis and its decision to abandon Aduhelm and cease clinical trials immediately. Biogen's stock dropped from \$320.59 on March 20, 2019, to \$226.88 at market's close on March 21, 2019, its worst day of trading since 2005. The market's reaction to the news was a clear reflection of the reality that Biogen had nothing to show for a significant investment in what it had expected to be a new blockbuster drug.

49. In May of 2019 a Biogen executive 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 and against FDA procedures. Thereafter Biogen's lobbying campaign of the FDA was referred to within Biogen as Project Onyx. The early meetings between the FDA and Biogen were revealed in an investigative report by Stat News on June 29, 2021. Biogen and the FDA's communications and conduct during this period are the subject of ongoing investigations by the FTC, SEC, multiple Congressional Committees, and the Office of the Inspector General of U.S. Department of Health and Human Services.

50. On June 14, 2019, Sandrock formally met with Dunn regarding submission and approval of Aduhelm. At the meeting, Sandrock was allegedly assured the FDA would not deem Aduhelm ineffective, and FDA recommended 5 potential paths to getting Aduhelm through the approval process. From June 15, 2019, through October of 2019, representatives of Biogen and the FDA met regularly to discuss Aduhelm.

51. On October 22, 2019, in a complete reversal from its prior statements to investors in March 2019, Biogen announced it would seek FDA approval for Aduhelm. Biogen justified the

reversal as being based on what Defendant Vounatsos then described as “additional analysis” of data from the clinical trials that Biogen believe showed that, contrary to its earlier futility analysis, the drugs were effective and likely to be approved. Sandrock called the decision “a turning point for patients, caregivers, physicians and scientists in the fight against Alzheimer's disease.”

52. Biogen completed its submission of Aduhelm to the FDA on July 7, 2020. Biogen announced the completion of its submission in its Form 10-Q filed July 22, 2020. In conjunction with that filing, Biogen held a conference call to announce its earnings and take questions from investors. During the call, Defendant Vounatsos announced for the first time that Biogen “[had] started to make progress engaging with payers and defining [Aduhelm]'s value proposition.

53. On November 6, 2020, the PCNS Advisory Committee met to consider Aduhelm. By a vote of 10 – 0, with one member abstaining, the panel recommended that the FDA not approve Aduhelm based on the lack of proven clinical benefit and safety risks to patients receiving the treatment. While the recommendations of advisory committees do not bind the FDA, the FDA usually follows the recommendation of the panel, and the unanimous opposition to approving Aduhelm was seen by the market as very negative development. Indeed, prior to the FDA’s approval of Aduhelm, the agency had never approved a drug or treatment unanimously opposed by such an advisory committee.

54. Despite Aduhelm’s public repudiation by the PCNS Advisory Committee, Biogen continued to tell investors they were confident about Aduhelm’s eventual approval and continued to spend money on preparing for commercialization of the treatment once it attained approval.

C. Defendants’ Pre-Class Period Statements Primed the Market to Expect Sales of Aduhelm to Take Off Immediately Following FDA Approval

55. On February 3, 2021, Biogen filed Form 10-Q with the SEC for the 4th Quarter of 2020 and held a conference call to discuss its earnings with investors (the “February 3, 2020,

Earnings Call”). In the February 3, 2020, Earnings Call, Defendant Vounatsos described the then current status of Aduhelm’s commercialization efforts: “We remain ready to launch [Aduhelm] in the U.S., if and when it is approved.”

56. In addition, Defendant Vounatsos discussed the work being done to determine the eventual price of Aduhelm:

Concerning price, we are getting there. We had very large engagements with many stakeholders. And basically, there are 2 main dimensions. The first one is the clinical meaningfulness and potentially in terms of cognitive functions, but also functional aspects on activity of daily living. This is one side of the equation.

The second one is the cost of Alzheimer’s to society, which is nowadays more than \$550 billion a year in the U.S. The cost for caring for patients, and if I’m not mistaken, it’s more than \$0.5 million. By the age of 80, 75% of the patients are in nursing home and this costs more than \$100,000 a year. And these are the main elements that we consider in our wide engagement on the important topic of price. We are getting there, as I said, but too early to give more specifics.

57. These statements were designed to inform investors that, once the FDA approval Aduhelm, Biogen would be ready to immediately begin selling the drug as it was priming the medical community to begin prescribing it.

58. Defendant Vounatsos participated in a conference for the healthcare sector put on yearly by the investment bank Cowen on March 1, 2021. During the conference, Vounatsos took questions from analysts regarding Biogen’s business and continued to update investors regarding Biogen’s work to launch Aduhelm. He said, “And while we speak, Biogen is ready to launch [Aduhelm].”

59. Finally, Vounatsos described Biogen’s work on determining a price for Aduhelm:

And we are set with price. We are ready and following a very thorough work done by the team, and we are working to ensure potentially an equitable launch so that we can take care of the underserved populations and learn from the COVID crisis. So Biogen is ready.

So the price, the team has done a very thorough work on assessing, potentially, the value for [Aduhelm] by looking at the clinical meaningfulness based on our data, but also the

burden to the society in terms of cost, nowadays, assessing the U.S. more than [USD 850 billion] a year in terms of direct and indirect costs. But in addition, we know that 75% of the patients affected at the age of 50 -- at the age of 80 have to be institutionalized. And it costs more than \$100,000 a year to keep those patients in institutions, in addition to the emotional impact it has on the caregivers, on the family. So it's a societal, I would say, issue. And these are key consideration in order to assess the value. The market is extremely large.

Based on the entry criteria of our Phase III studies, it's more than 10 million patients in the U.S. only. Obviously, it doesn't mean that all the patients qualify, it doesn't mean that all the patients are known from the healthcare system. Some of them are not known. So the epidemiology is absolutely tremendous. It's a multi-billion dollar opportunity, certainly, for the company. But again, more importantly, we are talking about the value in terms of cognition and function to the patients directly, to the caregivers also. [Emphasis added.]

60. Vounatsos' statements conveyed to investors that Biogen was ready to commence commercial sales of Aduhelm upon approval by the FDA. Investors thus understood that all that was in the way of Aduhelm being prescribed was FDA approval.

61. On April 7, 2021, the FDA's Medical Policy and Program Review Council met to discuss whether to approve Aduhelm. Though it was not announced to the public at the time, they joined the FDA Advisory Panel and recommended against approval. As discussed below, after the Council recommended against approval, Biogen was informed that FDA staff would recommend approval via the Accelerated Approval process.

62. On April 22, 2021, Biogen released their Q1 2021 earnings and held a conference call for investors and analysts (the "April 22, 2021, Earnings Call"). In the call, Vounatsos discussed Biogen's latest progress on preparing for an approval of Aduhelm and the work done to commercialize the treatment.

63. In the April 22, 2021, Earnings Call, Vounatsos claimed:

We are ready to launch aducanumab in the U.S. should we receive the regulatory approval, and we anticipate an FDA decision by the June 7 PDUFA date. If approved, aducanumab will be the first therapy to meaningfully change the course of Alzheimer's disease and will represent a significant growth and value creation opportunity.... We have identified and evaluated key sites of care that have the necessary infrastructure for Alzheimer's patients.

We believe that more than 600 of these sites will be ready to treat patients shortly after a potential approval.

64. Also, on the April 22, 2021, Earnings Call, Vounatsos laid out Biogen's value proposition for Aduhelm (while the treatment's price remained confidential):

Alzheimer's creates a cost burden of over \$600 billion per year in the U.S. and the costs for caring for an Alzheimer's patient can be over \$0.5 million. Alzheimer's deprives many patients of their independence. By the age of 80, approximately 75% of people with Alzheimer's disease live in a nursing home at a per patient cost of approximately \$100,000 per year. The potential approval of aducanumab will be an unprecedented milestones for patients, their families and society at large.

65. Finally, in the same April 22, 2021, Earnings Call, Vounatsos claimed:

Concerning price, I think that we are there, Mike. We have done a thorough engagement with different stakeholders, considering the burden of the disease and the clinical meaningfulness that aducanumab will bring. And we have engaged with pharmacoeconomics including ICER many times and orders in the US and beyond.

D. The FDA's Controversial Approval of Aduhelm

66. On June 7, 2021, the FDA approved Aduhelm under the Accelerated Approval process. The Accelerated Approval was justified based on Aduhelm's effects in reducing amyloid beta in patients, not in preventing cognitive decline. The FDA determined that the reduction of amyloid beta was an acceptable bio-marker for efficacy of the treatment to justify Accelerated Approval. Additionally, the FDA approved a broad label for Aduhelm, 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 was required to complete a Phase IV study within 9 years to determine the efficacy of Aduhelm in-use.

E. Biogen Announced the Launch of Aduhelm

67. The FDA publicly announced the granting of Accelerated Approval to Biogen to begin commercial sales of Aduhelm in the United States on June 7, 2021. Biogen's stock trading

was halted that morning, pending the FDA's decision. After the decision was announced, Biogen's stock price skyrocketed.

68. 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 resulting in its market capitalization rising by approximately \$14.6 billion on June 7, 2021.

69. Analysts touted the announcement as a game changer for Biogen. Noah Higgins-Dunn of Questex titled his note "Biogen's aducanumab crosses FDA finish line just in time to save its business" and noted "the company's all-in bet on aducanumab comes amid serious troubles elsewhere in its business." In a follow-up report the same day, Higgins-Dunn quoting other analysts noted:

Aduhelm could reach \$10 billion in peak sales, Bernstein analysts said in their note. Meanwhile, Cantor Fitzgerald analysts wrote Biogen 'is now set up for one of the biggest drug launches in biopharma history.' The investment bank predicted peak sales of roughly \$8.2 billion in 2028.

70. Yatin Suneja of Guggenheim issued a flash notice on the news noting especially that "900 infusion sites in the U.S. are now ready, and BIIB expects the drug to be available in the next 10 – 14 days." Oppenheimer noted "our SOTP analysis values Aduhelm at \$200/share, contributing 45% to our \$450 PT." MorningStar was similarly enthusiastic, noting "[w]e've raised our fair value estimate for Biogen to \$401 from \$350 following this news."

71. In initially discussing the FDA's approval, Bloomberg Business News reported on June 7, 2021, that analysts estimated that "[a]nnual sales could peak at \$5 billion." In an interview with Bloomberg Business News that same day, Vounatsos said that Biogen had already produced millions of vials of Aduhelm and it would hit the market within 10 days to two weeks. He also

reportedly said that “over 900 infusion sites in the U.S. were prepared and ready to administer the drug,” which Biogen announced would be priced at \$56,000 per year.

F. Defendants’ False and Misleading Statements

72. Following the FDA’s approval of Aduhelm, Defendants’ made three categories of false and misleading statements, and omitted to disclose material facts necessary to make the statements that were made not misleading, regarding the commercial viability of Aduhelm: (i) that Biogen had “engaged” and “consulted” with payers on the price for Aduhelm and received their input during the process of setting the price; (ii) that Medicare coverage for Aduhelm was “automatically presumed” with FDA approval; and (iii) after CMS announced it would undertake an NCD analysis, that MACs and MA plans “will provided coverage” of Aduhelm while the NCD analysis was pending.

1. Defendants Falsely Represented that Biogen Had Engaged with Payers on the Price of Aduhelm

73. After Aduhelm’s FDA approval on June 7, 2021, Biogen announced that the wholesale acquisition cost of the treatment, involving an infusion once every four weeks, would be \$4,312 per infusion for an average patient, and estimated that the cost of the maintenance dose of 10mg per kg would total \$56,000 annually for such a patient.

74. Defendant Vounatsos, during an interview with CNBC’s Power Lunch on June 7, 2021 misrepresented that Biogen received input from payers on pricing Aduhelm:

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.... 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.

75. The next day, June 8, 2021, during a special conference call scheduled for the launch of Aduhelm, Vounatsos again misrepresented that Biogen had consulted with payers on the pricing Aduhelm before arriving at the \$56,000 yearly price tag for Aduhelm:

In determining the price, we engaged with stakeholders, including clinical experts, health economics, 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 4 years.

76. The first question during the call came from Evercore ISI analyst Umer Raffat, who pointedly observed, “I do think there’s a disconnect between some of the words that you’ve shared in your press releases like responsibility, access, health equity versus the price point, especially given the primary care population,” before asking, “can we perhaps dig into a little more detail on the thought process behind the price point, the \$56,000, considering it’s a primary care population, considering there’s no outcomes benefit?” Vounatsos answered in reference to the value Alzheimer’s treatment provides to society before “ask[ing] Chirfi Guindo to **tell you a bit more about our work and price setting.**” (Emphasis added.) Guindo also misrepresented that Biogen had consulted with payers on the pricing of Aduhelm:

Just to give a bit more background in terms of our thinking, Umer, we’ve been at this for months, as Michel suggested. **We’ve consulted extensively with** experts, health economists, clinicians, policy and **payer leaders.** And we have taken also into consideration the Biogen pricing principles.... So we consider this to be a really responsible price, and we consider this to be a price that is sustainable for the system. (Emphasis added.)

77. Each of these statements were materially false and misleading when made, and omitted to disclose material facts necessary to make those statements not misleading. Biogen never consulted with or sought input from payers on the price of Aduhelm prior to June 7, 2021. Biogen

discussed Aduhelm's value proposition to society, a marketing pitch meant to place the focus on the potential savings to society of a potential treatment for Alzheimer's. As discussed more fully below, by falsely representing that Biogen consulted and engaged with payers about the price of Aduhelm and omitting to reveal what Biogen actually discussed with payers about Aduhelm's price — that Biogen pitched payers and experts on Aduhelm's overall potential benefits to society, and not its actual price per patient — Vounatsos, Guindo and Biogen misled investors as Biogen did not receive any input from payers on Aduhelm's pricing.

78. The market understood these statements by Vounatsos and Guindo to convey that Biogen had received input from payers in the process of deciding Aduhelm's price. Michael Yee, an analyst at Jefferies who closely followed Biogen, testified at his deposition that he understood Vounatsos' statements about the \$56,000 per year price to convey "that it would have been a price that they had discussed with those folks." Ex. 25² (Yee Tr.) 63:23-24.³

79. Vounatsos and Guindo knew Biogen did not engage or consult with payers on Aduhelm's price.

80. An early draft of a June 7, 2021 CEO letter originally stated that Biogen had consulted with insurers and other payers about Aduhelm's price. Ex. 1.

81. Gassenbach, Biogen's Head of Corporate Affairs and Corporate communications, wanted to vet this statement with team members who worked on this issue. Ex. 1. In an exchange

² Citations to "Ex." are to the exhibits to the concurrently filed Declaration of Jeffrey C. Block in Support of Lead Plaintiff's Renewed Motion to Amend the Complaint in Light of Evidence Produced in Discovery.

³ Yee clarified upon further examination by counsel for Defendants that his testimony about the meaning of the statement reflected his present interpretation of the statement, and that he could not remember "specifically or exactly what I was thinking on June 8, 2021." Ex. 25 (Yee Tr.) 138:9-16.

of emails beginning June 4, 2021 and continuing through June 6, 2021, however, it became clear that Biogen *never* engaged with or consulted with payers—government or private—on pricing Aduhelm. Ex. 1.

82. In response to seeking feedback from Brendan Manquin, VP of US Market Access and Reimbursement, on the CEO letter, Manquin wrote on June 4, 2021, that “I don’t think we can say ‘We have consulted extensive with [...] insurers and other payers about ADUHELM’S price,’” Gassenbach responded that “Chirfi [Guindo, Executive VP and Head of Global Marketing, Market Access and Customer Innovation,] feels strong about [including that statement].” Ex. 1. Manquin responded, “I don’t think we can substantiate [that statement]. Ex. 1. If they ask us who we consulted with we will have no answer.” Gassenbach wrote back that “Chirfi mentioned all the advisors we worked with when I asked...” Ex. 1. To which Manquin replied, “**We never discussed price with them.**” Ex. 1. (Emphasis added.)

83. Chris Leibman, Senior VP, Value, Access, Public Policy and Government Affairs, who was also on the thread, added, “Better if we say spoke about ‘value’ or ‘value and pricing.’” Ex. 1. On June 6, 2021, Chris Leibman revisited the thread to ensure “the IR [Investor Relations] Q&A reflects same language as script, consistent with what [was revised] on Friday. Ex. 1. **We don’t want to imply payers support or defend our price.** I would not use 2nd bullet for #7.” (Emphasis added.) Ex. 1.

84. This second bullet, the one Leibman instructed to not use, read, “It is important to note that payers were part of the initial group of stakeholders that were engaged as Biogen was developing the ADUHELM price.” Ex. 1. He also added that the phrase “**In determining the price,** we have taken into consideration the perspectives of various stakeholders and have consulted extensively with ... payers” should be rephrased to begin, “**In understanding**

Aduhelm[?] value to support our price, we have taken into consideration...” Ex. 1 (Emphasis added.) Gassenbach closed the loop on the evening of June 6:

Message

From: Natacha Gassenbach [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E3009038B1B0471F83043BB03884B9BA-NATACHA GAS]
Sent: 6/6/2021 7:27:50 PM
To: Laura Keller [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58995cbab8e8465bb2645e7bd84339b7-Laura Kelle]; Nicholas Simmons-Stern [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=879896620dc4447c8bd71e3d0414ee63-Nicholas Si]; Chris Leibman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=058dba3d3569451291dd9ecad11148ca-Chris Leibm]; Brendan Manquin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f88590a90074a4d94aed4fb8ff979f4-Brendan Man]
CC: JC Molina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa2760e72be744eebbf5c8041567dc0e-JC Molina]; Mike Hencke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c644214a6fb4587a7bced5b2458b4f9-Michael Hen]; Dana Conti [dana.conti@biogen.com]
Subject: RE: CEO Letter FYI
Attachments: CONFIDENTIAL V2 Draft CEO Letter 6-6-21 Post OPDP team reviewed.docx

Team

I wanted to assure you that the CEO letter and the script have the correct language. (attached)

It is too late to change the Q&A already distributed to the executives. All of them were in conversation where these points were discussed and I am confident they will auto-correct.

I am checking the ELT talkings points and ensure the edits are made there.

Best

Natacha

Ex. 1. As Gassenbach’s email back to the group explained, while the IR Q&A provided to the executive team, which included Vounatsos and Guindo, included the language about engaging with payers about Aduhelm’s price, the CEO letter was altered and all of the executives “**were in conversation where these points [about engaging with payers about price] were discussed**

and I am confident that they will auto-correct.” (Emphasis added). Despite being told otherwise, neither Vounatsos nor Guindo “auto-corrected.”

85. Gassenbach testified during her deposition that she discussed the CEO letter with Guindo and, specifically, the change in language about engaging with payers on Aduhelm’s price. Ex. 26 (Gassenbach Tr.) 164:13-22. Gassenbach further testified that she assumed Vounatsos would be briefed on the change, saying “it was my assumption that executive [sic] would be prepared and briefed on the appropriate response on the topic that I discussed into this email thread.” Ex. 26 (Gassenbach Tr.) 175:23-176:2.

86. At their depositions, Vounatsos and Guindo testified unequivocally that Biogen never consulted with or sought input from CMS and other payers on the price of Aduhelm. Instead, as both explained, Biogen pitched CMS and other payers on the anticipated value to society of a treatment that effectively slowed the progression of Alzheimer’s Disease.

87. Guindo was explicitly asked about the language in the draft CEO letter, which claimed Biogen had engaged with payers on price. Guindo testified, “So first of all, **this statement, as it is written here, is incorrect in the sense that we were not consulting about Aduhelm’s price.** We were consulting about Aduhelm’s value.... Leibman corrects it.” Ex. 27 (Guindo Tr.) 57:25-58:7 (emphasis added). And when asked whether it would be correct to have said Biogen consulted extensively with insurers and other payers about Aduhelm’s price, Guindo answered, “About the specific price of Aduhelm, that is incorrect. As far as I recall it was really about the value of Aduhelm.” Ex. 27 (Guindo Tr.) 58:22-59:4. Guindo confirmed that he agreed with the changes made to the draft CEO letter to remove reference to engagement with payers on price. Ex. 27 (Guindo Tr.) 59:18.

88. When asked whether Biogen’s teams under Alisha Alaimo discussed the \$56,000 a year price before FDA approval, Vounatsos answered, “No. We cannot do that,” and clarified, “We cannot communicate to one body or one individual something that is not communicated to the world in terms of price. **So we discussed value. We did not discuss price.**” Ex. 28 (Vounatsos Tr.) 144:4-9 (emphasis added). Later, when explaining what he meant by his statement “we are pleased with the level of engagement” with public and private payers, Vounatsos stated, “we did not discuss the price.” Ex. 28 (Vounatsos Tr.) 146:22-23. He was emphatic in reiterating this point:

Q: But just so I’m clear, in your discussions with either [HHS] Secretary Azar or with CMS, did you discuss hypothetical price points with them?

A: Absolutely not.

Ex. 28 (Vounatsos Tr.) 150:4-7.

89. Vounatsos specifically denied receiving input on price from the public officials responsible for administering Medicare:

Q: In your discussions with Secretary Azar or CMS did you receive any input from them on an appropriate price point?

A: No.

Q: And do you know if anyone from the Biogen team received any input from CMS on an appropriate price point?

A: No.

Ex. 28 (Vounatsos Tr.) 150-51:22-4.

90. Manquin testified with equal clarity. He said, “we did not” ever discuss the actual price or proposed price of Aduhelm with CMS and “did not” get the agency’s input on what a price point for the treatment should be. Ex. 29 (Manquin Tr.) 131:17-132:2. Manquin testified that “the

actual final price of \$56,000 ... we had not shared that with any external party. We had not shared that with any payers. We had not shared that with CMS.” Ex. 29 (Manquin Tr.) 167:7-11.

91. Indeed, a confidential presentation given to the Board of Directors on June 2, 2021, five days before the FDA approved Aduhelm, included a slide—presented by Guindo—titled, “Key Considerations for Price Determination,” which said “We have consulted with expert Clinicians, Patient Advocates, Health Economists and Policy Leaders to guide our work on ADUHELM Value and have anchored our recommendation on Biogen’s Pricing Principles....” Exs. 2, 3. Conspicuously absent from this internal Board presentation was any representation that Biogen consulted with payers, including CMS, on Aduhelm’s pricing.

92. As Vounatsos, Guindo, and Leibman all explained, Biogen’s interactions with the “government payer,” CMS—which is charged with overseeing Medicare and Medicaid—never included discussing a price for Aduhelm. Instead, Biogen instead pitched payors on the value to society of a treatment that effectively delayed the progression of Alzheimer’s disease. It was a marketing pitch based on a series of assumptions about the benefit Aduhelm might be able to confer upon certain Alzheimer’s patients (but which the trial data did not clearly support). Biogen lobbied CMS to view Aduhelm’s to-be-announced price through the lens of its potential overall value to the health care system—the costs saved by reducing the expense of moving Alzheimer’s patients in nursing homes and the costs of home care.

93. In May 2020, Jim Meyers—a former pharmaceutical executive at Boston Consulting Group who worked closely with Biogen executives and middle management in strategizing around the launch of Aducanumab since at least early 2020—shared his thoughts on arranging a series of “Key Stakeholder Forums in advance of launch,” which included focusing on “The ‘cost’ of AD (medical and societal, direct and indirect, and how <1% of costs today are spent

on drug therapy)” and the stark warning that “***** **Under no circumstances would I recommend communicating or socializing the price of ADU in advance of launch.**” Ex. 4. Meyers flagged as an important issue that the “**value proposition [is] more compelling at ‘30,000 feet’ than at ‘5,000’ feet (i.e., more compelling at the societal level than at the individual payer level.)**” Ex. 4. Meyers sent his advice to Guindo, Leibman, and (among others) two external advisors who worked closely with Vounatsos and whose opinions he valued: Per Wold-Olsen and Per Lofberg. Ex. 5.

94. On September 15, 2020, Vounatsos met with Seema Verma, the Administrator of CMS in the Trump Administration, and three other high ranking agency officials—Calder Lynch, Meredith Good-Cohn, and Mark Atalla. Ex. 6. His prepared talking points included the “Aducanumab Value Story”: “If you keep patients healthier longer, Aducanumab has the potential to reduce *institutionalization*, hospitalizations, and caregiver hours, leading to a cost-effective product that delivers *significant value to Medicare* and society.” Ex. 7 (emphasis in original). And “Value Story Additional Information”: “Aducanumab will lead to 100,000 fewer nursing home admissions and \$14B/year reduction in national LTC expense[;] ... expected drug costs will remain a small fraction of total AD spend[;] Even at peak, Aducanumab will account for <X% of total direct medical costs spent on AD in the US[;] Aducanumab is the start of a cycle of innovation, with more efficacious medicines to follow.” Ex. 7. The slide deck accompanying his presentation to Verma highlighted “AD is One of the Most Expensive Diseases in the United States,” projecting \$305 Billion in Direct Costs will be spent on AD and other dementias in 2020, with direct costs “surpass[ing] \$1.1 trillion by 2050” if “unaddressed.” Ex. 8. The slide deck also said, “Delaying the onset of AD could result in significant cost savings—\$219 billion at 1 year, \$415 billion at 3 years, and \$599 billion at 5 years.” Ex. 8.

95. Then, on January 4, 2021, Biogen submitted its CMS Briefing Book on Aducanumab. Ex. 9. This Briefing Book again emphasized the “Overall Cost Burden” to society of dementia—“The total estimated direct medical costs related to dementia were \$109 billion in the US in 2010, which are projected to increase to \$259 billion in 2040”—and the “Impact on Medicare/Medicaid Costs”—“Healthcare payments in the US for dementia due to AD or other dementias is expected to total \$305 billion in 2020, 68% (\$206 billion) of which are expected to be covered by Medicare and Medicaid.... [In 2019,] Total average annual payments for beneficiaries with dementia due to AD or other dementias were \$50,201, vs \$14,326 for beneficiaries without dementia due to AD or other dementias.” Ex. 9.

96. Biogen never included *any* information on potential pricing for the Aduhelm treatment. Biogen sought to persuade payers that any price was palatable relative to the societal cost of caring for Alzheimer’s patients.

97. As explained *infra*, the false representations that Biogen had engaged or consulted with payers on price was of particular significance because Biogen understood that even though price is not technically part of Medicare’s “reasonable and necessary” standard for coverage, in practice “CMS will care about price,” and “[t]he higher the price, the greater the scrutiny.” Ex. 12. And, as Manquin explained to Alaimo in a May 10, 2021 email, “Although cost is not explicitly a criteria [considered by CMS for Medicare coverage], in practice NCD processes are only undertaken where there is a significant concern about budget impact.” Ex. 22. Biogen understood, by November 13, 2020, that at an annual price of \$55,000, Aduhelm could double the Medicare budget for drug coverage. Ex. 23. By misrepresenting that Biogen had engaged with payers on setting the price of Aduhelm Biogen concealed the likelihood that a massive budgetary impact could lead to CMS limiting coverage of Aduhelm.

98. Accordingly, Vounatsos' and Guindo's statements also omitted to reveal the material facts that Biogen's engagement with payers consisted only of lobbying them on the overall value to society of a treatment that could meaningfully slow the progression of Alzheimer's disease and thereby reduce the costs to care for Alzheimer's and dementia patients.

2. Defendants Falsely Represented that Medicare Coverage for Aduhelm is "Automatically Presumed with FDA Approval"

99. During the June 8, 2021, Conference Call, in his opening remarks, Vounatsos misrepresented that Medicare coverage was "automatically presumed" following FDA approval:

One critical near-term priority for the launch will be securing payer coverage. The vast majority of Alzheimer's patients in the U.S. 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.** Biogen is committed to an equitable launch with a goal of maximizing access for all patients with early stage Alzheimer's disease, including the underserved population with can be disproportionately impacted.

(emphasis added).

100. Later during the call, Cowen analyst Philip Nadeau asked, "One question from us on your discussions with payers, particularly Medicare. What do you expect the insurers to do to limit access?"

101. Alaimo answered, also mispresenting that Medicare coverage is "automatically presumed with FDA approval":

That is a tough one *because it's not one we can really speculate on at this stage*, but I do have a couple of things I can share with you. Prior to launch, our teams have been working closely with both commercial and government payers. And what I can tell you is that our commercial teams will be discussing patients consistent with those studied in ADUHELM's clinical development program with their customers. Now we've already talked about the majority of patients being on Medicare. **And for Medicare fee-for-service, coverage is automatically presumed with FDA approval, and we expect most Medicare Advantage and commercial plans to define their medical policies, which is in reference to your question, within the first several months after launch.**

(emphasis added).

102. The statements that “coverage is automatically presumed with FDA approval” was materially false and misleading when made. Vounatsos and Alaimo knew, or recklessly disregarded—based on information and feedback from various Biogen executives, and based on information provided to Biogen’s Board of Directors at a meeting attended by both Vounatsos and Alaimo regarding coverage for Aduhelm—that (1) CMS would open an NCD if FDA approved Aduhelm with a broad label; (2) CMS would heavily scrutinize Aduhelm given questions regarding Aduhelm’s efficacy and the large budget impact resulting from Aduhelm’s price and broad label; and (3) there was a high risk that the NCD would result in highly restrictive and commercially unviable coverage.

103. Medicare coverage follows a complex regulatory process, and, as explained below, Defendants uniquely understood that the two facts most responsible for Aduhelm’s much-hyped blockbuster commercial opportunity—the FDA’s broad label and the high \$56,000 annual price tag—created the two largest risks to obtaining Medicare coverage for Aduhelm. Defendants also understood that in the case of CMS beginning a NCD, MACs, Medicare Advantage providers, and commercial plans would (1) likely follow CMS’s lead and wait to define plans or cover claims and (2) employ administrative review tools to slow and deny reimbursement of claims.

104. The possibility of an NCD for Aduhelm was neither hypothetical nor remote; in fact, Biogen expected an NCD. NCDs are not uncommon in circumstances where a treatment (1) is approved under the Accelerated Approval process by the FDA, (2) is expensive, or (3) where there is controversy surrounding a treatment’s efficacy, side effects, or safety. Aduhelm fit the bill perfectly.

105. As early as February 15, 2019, Brendan Manquin and members of his Market Access and Reimbursement (MA&R) team presented to Alaimo on the Company's "CMS Engagement Strategy Update," and one of the slides starkly explained that "FDA Approval \neq CMS coverage" because "FDA evaluates whether a drug is 'safe and effective,' but "CMS assesses whether a drug is 'reasonable and necessary.'" Ex. 10. And while "Medicare does not explicitly consider cost or budget impact in making coverage determinations," Biogen understood even then that price and budget impact influence CMS's review. Ex. 10. The same presentation identified "Risk Factors that Biogen CANNOT Control," which included that "Medicare coverage of aducanumab will be based on the readout of the pivotal [ENGAGE/EMERGE] studies" and "We anticipate that MACs and MA plans will be consistent in their push for CMS to undertake an NCD." Ex. 10. The MA&R team's next steps related to CMS engagement included "prepar[ing] for an update meeting in March to support discussions with Michel [Vounatsos] and the executive committee." Ex. 11.

106. On July 17, 2020, Biogen invited numerous outside experts, including former CMS and FDA leaders, the heads of multiple Alzheimer's patient advocacy groups, and the chief medical officer of Cigna to a Biogen internal only Public Policy Roundtable to discuss Aduhelm and strategies around bringing the drug to market. Ex. 12. Vounatsos gave the opening remarks. Ex. 12. Mark McClellan, a former CMS Administrator and FDA Commissioner, "stated that CMS will base their coverage on the FDA label." The experts "emphasized that the broader the label, the higher the probability of payers creating policies and hurdles to minimize utilization," that "aducanumab will be heavily scrutinized in a Democratic Administration, House and Senate," and "that CMS will care about price, volume and duration of therapy." Ex. 12. All advisors again "emphasized the importance of the upcoming election and the potential cost to Medicare" because

“this would be the ‘first major hit to the Medicare program in decades’ and would be ‘scrutinized very aggressively.’ ‘The higher the price, the greater the scrutiny.’” Ex. 12.

107. Biogen’s internal Aducanumab PDC team expected—as far back as July 2020—that in case of FDA approval with a broad indication for Aduhelm (which was the agreed-upon “base case” with the Company’s executive committee), CMS would engage in a NCD —“typically a 12-18 month process” that would lead to “likely narrower [coverage] than what the indication statement would lead us to.” The minutes to the July 29, 2020 Aducanumab PDC team meeting, indicate that notwithstanding the expected NCD that would follow a broad indication, the team decided not “to push back on broad label internally or with the regulators” but that it was “[n]ecessary to have a discussion with the EC [Executive Committee] to reconfirm and ensure alignment with the base case....” Exs. 13, 14.

108. And following the FDA Advisory Committee hearing in which the committee members unanimously voted against FDA approval of Aduhelm, Biogen prepared a new presentation on “Adnucamub US Pricing: Strategic Considerations” in November 2020. Ex. 15. Leibman sent an updated “draft BOD deck for future use” to Guindo “[a]s a follow up to our discussion this morning.” Ex. 16. Headlining the presentation was the recognition that “With heightened uncertainty and scrutiny following the Advisory committee, we must consider an expanded range of US payer/stakeholder response to regulatory approval,” and “Potential Risks include:” “Non-coverage or highly restrictive NCD; OR non-coverage or highly restrictive [local coverage determinations (LCDs) / independent Med. Advantage / commercial medical policy” and “Coverage with Evidence Generation (i.e., mandated by CMS).” Ex. 15.

109. On May 10, 2021, Maquin emailed Alaimo with the disclaimer “***Please do not forward***” right up front. He wrote, “I gather there will [be] a discussion about CED at the EC

[Executive Committee] update today. I wanted to make sure you had appropriate background for this conversation. Sorry it's long; this is nuanced and complicated.” Ex. 29. Manquin began with background: “Medicare coverage is limited to items that are ‘reasonable and necessary’ for the treatment or diagnosis of an illness or injury (i.e., can demonstrate clinical effectiveness within the Medicare population).” Ex. 22. After explaining the ways Medicare can determine the contours of “reasonable and necessary,” Manquin explained how NCDs come about and their possible outcomes:

- NCDs are triggered where there is a combination of significant pressure from local MACs/Medicare Advantage plans and federal policy-makers to clarify for what patients a drug is ‘reasonable and necessary’ (i.e., has a proven clinical benefit)
 - Although cost is not explicitly a criteria, in practice NCD processes are only undertaken where there is a significant concern about budget impact
 - CAR-T and Provenge were recent examples
 - NCD can have several outcomes: Covered with/without restrictions; Non-covered; or “National Coverage with Evidence Development Requirement” – aka CED
 - CMS makes coverage decisions involving CED after a formal review of the evidence
 - A diagnostic or therapy is covered under CED in the context of: i) approved clinical study; ii) collection of additional clinical data. ***ALL*** patients must be included in the trial to receive access – it is not sufficient to have a subsample
 - CEDs are rare. Currently there are 22 NCDs with CEDs (out of 346 NCDs)
-

In order to have a CED on aducanumab, Medicare would need to initiate and complete an NCD, which would take 12-18 months after initiation.

Although I don't consider CED to be the most likely outcome, a label that left significant uncertainty around the clinical benefit and/or the relevant patient set, would certainly increase the risk. A robust post-approval data generation plan could address potential CMS concerns around data and “head off” a CED.

Ex. 22. Alaimo wrote back thanking Manquin: “Thank you, Brendan. Really appreciate it.” Ex. 22. Manquin drafted a version of this email with Elizabeth Kinter, Senior Director US Market Access and Reimbursement, on May 7, 2021 and sent the draft to Amy Demske, Senior Director Federal Executive Branch Strategy, and Stephanie Dyson, VP Public Policy and Government

Affairs, for their input, with the disclaimer, “Also, let’s not downplay the risk of CED too much—there are still label scenarios where it could occur (and also it’s bad karma!).” Ex. 24.

110. On June 3, 2021, Alaimo, Manquin, Deb Glasser, VP Alzheimer’s Franchise US, and Ivana Rubino, VP Alzheimer’s Medical US & Global Medical, presented the “Aducanumab U.S. Launch Update” to the Board of Directors. Ex. 17. Vounatsos attended this Board meeting. The “Reimbursement Overview,” presented by Manquin, explained that “CMS coverage is presumed upon FDA approval,” but “CMS may invoke authority to issue National Coverage Decision (NCD) that may limit, or deny, Medicare coverage for an item or service if deemed to have insufficient clinical benefit for Medicare patients.” Ex. 17. Although “[o]nly 4 NCDs have been initiated for drugs in last 15 years,” the “[r]easons included lack of confirmed clinical benefit and substantial budget impact.” Ex. 17. The “NCD process could lead to Coverage Limitations or Coverage with Evidence Development. (CED).” Ex. 17. The presentation further informed the Board that MACs could “limit or deny coverage” within their regions. *Id.* The presentation then provided “[c]urrent assumptions influencing coverage pathway actions”: Biogen assumed FDA would approve Aduhelm with a broad indication for “Treatment of Alzheimer’s Disease” through the “Accelerated Approval Pathway,” the “potential implications” of which “on CMS Coverage Actions” included CMS’s general “[d]esire for coverage to align with clinical trials” and “Public scrutiny on CMS spend on accelerated approvals.” Ex. 17. Acknowledging that the “Primary Manuscript” of the pivotal studies was “Currently Unpublished,” Biogen acknowledged that “CMS requires peer reviewed published data.” Ex. 17. And related to “Pricing,” Biogen recognized the “Budget Impact” would lead to “High scrutiny from current administration.” Ex. 17. So, Biogen prepared for the probability that, “If broad label, payers will request NCD,” and MAC coverage would come “Potentially with Slow Claims Processing.” Ex. 17.

111. In sum, Defendants misled investors by representing that Medicare coverage was “automatically presumed with FDA approval” when, with (1) the broad label Aduhelm received from the FDA, (2) a price forecasted to double the budget of Medicare Part B, (3) the absence of published clinical data, and (4) a new Democratic administration atop CMS, Biogen had already determined that CMS was likely open a NCD, and that an NCD would open the door to narrow coverage for Aduhelm.

112. Vounatsos’ and Alaimo’s statements that Medicare coverage is automatically presumed with FDA approval were false and misleading as they knew, or recklessly disregarded that CMS would likely undertake an NCD that could dramatically restrict coverage and, absent a national directive from CMS, MACs and MA plans would make their own coverage determinations (which could “limit or deny coverage” within their regions), meaning coverage was not “automatic.” These statements also omitted to reveal material facts, namely that, under the FDA approval conditions for which Biogen planned (and which occurred)—a broad label, questionable evidence of Aduhelm’s efficacy and large anticipated impact to Medicare’s budget—Biogen expected (1) CMS would open an NCD, (2) Aduhelm would receive high scrutiny from CMS under the Biden administration, and (3) MACs and MA plans would erect immediate barriers to payment. All of which established that Medicare coverage was not “automatic.”

113. Alaimo gave a false and misleading response to the analyst question regarding Biogen’s “discussions with payers, *particularly Medicare*. What do you expect the insurers to do to limit access?” when she replied: “That is a tough one *because it’s not one we can really speculate on at this stage*.” Alaimo did not need to “speculate” on how coverage could be limited. She knew exactly what CMS could do to limit access and knew the large budget impact, broad label and questionable evidence of efficacy would lead to scrutiny and coverage limitations: she

also knew the MACs were free to make their own coverage decisions, including denying coverage until CMS might direct otherwise.

3. Vounatsos and Alaimo Falsely Represented that MACs and Medicare Advantage Plans “Will Provide Coverage” of Aduhelm During the Pending NCD

114. CMS announced the opening of a national coverage analysis for monoclonal antibodies, i.e., Aduhelm, on July 12, 2021 and informed the public that an NCD had many different potential outcomes. The announcement also stated, “Currently, coverage determinations for aducanumab are being made at the local level by Medicare Administrative Contractors who represent 12 jurisdictions across the country.”

115. Prior to the issuance of the NCD, Guggenheim analyst Yatin Suneja wrote in a June 25, 2021 Flash Note that “despite what our payer expert communicated to us . . . BIIB [Biogen] is confident that regional fee for service Medicare contractors (MACs), which cover ~65% of all Medicare patients, *are obligated to cover the drug* now that it’s been approved (**physicians have a way to bill under a miscellaneous code and MACs are legally bound to cover what is ‘reasonable and necessary’ which means eligible patients are already starting on the therapy . . .**)” (emphasis in bold and italics added, emphasis in bold only in original).

116. Dr. Mark McClellan said, during a July 15, 2021 ICER/CTAF conference—livestreamed to the public and covered in an analyst report issued that day by Mizuho—that MACs “will likely push back on covering Aduhelm until an NCD has been issued” and that Medicare coverage of Aduhelm “is going to be pretty limited at least until” after the NCD is decided, so we are “not going to see very big numbers in the near term.” McClellan explained that “he believes most MACs are ‘saying no’ because they are likely waiting for the national decision.”

117. Vounatsos, on July 18, 2021, received an email summarizing analyst commentary from July 15 and 16, after Biogen's stock price fell by 6.8%, or \$23.90 per share. The summary reported on Dr. McClellan's statements noted above and that commercial insurers, such as UnitedHealth, would wait for CMS to decide the NCD before providing coverage for Aduhelm. Ex. 21.

118. In an effort to address these views, during Biogen's Q2 2021 earnings call on July 22, 2021, Defendant Vounatsos misleadingly told investors that Biogen expected MACs and Medicare Advantage plans to cover Aduhelm during the pendency of the national coverage analysis:

In terms of reimbursement, it is still the early days, and I'm pleased to say that we have seen the first examples of Medicare Advantage plans approving pre-authorization. We welcome the recent opening of a 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 of our 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.

119. In response to a question from Michael Jonathan Yee of Jefferies about "whether there's anything you can do with CMS to strike a deal or anything like that" with respect to "reimbursement, access," Alaimo repeated the misleading statement that Biogen expected MAC and Medicare Advantage coverage while awaiting the NCD:

Now, while this analysis is underway, coverage decisions will be made by Regional Medicare Administrative Contractors, as you know as the MACs, and the Medicare Advantage plan. **Based on precedent, we expect the MAC s and Medicare Advantage plans will provide coverage for ADUHELM.** Now, while NCD for drugs are rare, and the only recent example of a drug NCD analysis, which was CAR-T, both MACs and Medicare Advantage plans continued to cover these -- this product during the NCA process.

120. These statements that MACs and Medicare Advantage plans “will provide coverage” for Aduhelm during the NCD analysis were false and misleading when made, omitted to reveal material facts, and Defendants made these statements with reckless disregard for the truth. Neither Vounatsos nor Alaimo had any basis to support their “expectations” that the MACs and Medicare Advantage plans would provide coverage during the NCD period. In fact, Biogen’s understanding was that if CMS opened a NCD—an understanding that was communicated to both Vounatsos and Alaimo—MACs would hold claims and employ utilization review methods to slow coverage and payment until the NCD was decided. Vounatsos’ and Alaimo’s statements omitted to reveal that Biogen expected the MACs to (1) push back on coverage if Aduhelm were approved with a broad FDA label (it was) and (2) put up barriers to reimbursement until after CMS issued its NCD.

121. Biogen understood early on that MACs had the independent authority to determine their own coverage policies in the absence of a national decision from CMS. Commenting on a November 11, 2019 presentation titled “Aducanumab US Launch Plan Review,” Alaimo testified at her deposition that “they’re [MACs] all individual in nature and they can write their own policies for medication and access.” Ex. 30 (Alaimo Tr.) 37:20-21. Because of this, said Alaimo, “when you launch into Medicare, you hope that ... you don’t end up in a ZIP Code lottery ... [where] you have one jurisdiction that allows coverage and another one that would not.” Ex. 30 (Alaimo Tr.) 36:24-37:7. Indeed, Alaimo was also expressly informed in October 2020 that “with a broader label and complexities of a diagnostic coverage decision, we can expect MACs to employ ‘utilization review’ methods to slow coverage/payment.” Exs. 31, 32 at 5.

122. Vounatsos testified at his deposition that Alaimo was “battling” the MACs after FDA approval. Ex. 28 (Vounatsos Tr.) 111:24. “Q. When you say she [Alaimo] was battling the

MACs, what do you mean by she was battling them? A. No. What I meant in the positive terms is that she was -- patients were challenged to access a product by some MACs, and then I was a bit better educated on what a MAC was. ... Q. So after the FDA approved Aduhelm, did you come to learn that MACs were limiting access to reimbursement for Aduhelm? A. This was a spectrum where some MACs were allowing; some were not allowing. Some were making things difficult.” Ex. 28 (Vounatsos Tr.) 112:2-16.

123. Alaimo therefore knew that despite FDA approval, Medicare coverage was not “automatic,” and she knew that the MACs might not “provide coverage” during the NCD because MACs were free to make their own coverage decisions and policies regarding Aduhelm, including no coverage. As Vounatsos and Alaimo knew, some MACs were “not allowing” reimbursement and “some were making things difficult.” When they represented to investors that they expected the MACs “will provide coverage” during the pendency of the NCD, they knew facts to the contrary.

124. Prior information provided to Vounatsos also reinforced that MACs would not likely authorize coverage for Aduhelm while awaiting a decision from CMS. A September 15, 2020 Memo sent to Vounatsos and Guindo— which outlined their goals and talking points for a call that evening to discuss Biogen’s FDA submission for Aducanumab with CMS Administrator Seema Verma—listed the following obstacles to obtaining “clear and consistent coverage of Adu for Medicare beneficiaries aligned with the FDA label”: (1) MACs were “unwilling[] to engage until [FDA] approval,” and (2) Biogen “believe[d] MAC or MA plans will request NC[D] if label is broader than trial population..., an NCD takes a year to finalize,” and “[i]t is likely that MACs will hold claims to try and determine how to ID the patients most likely to benefit from treatment,”

which “sets up an immediate barrier to treatment and provider payment.” Ex. 7. (Emphasis added.)

125. The proposed solution was to ask for a CMS official’s “assistance in putting this issue on her monthly MAC call to highlight coding challenges and other potential issues that could lead to confusion among carriers/MA plans.” Ex. 7.

126. And in a May 10, 2021 presentation accompanying Vounatsos’s discussion with the Board of Directors regarding the ICER Draft Evidence Report on Aduhelm, the speaker’s notes on a slide titled “Presumed Coverage for Aducanumab” explained, “It is atypical for a [national or local] coverage decision to be issued but we know with a broader label and complexities of a diagnostic coverage decision, we can expect MACs to employ ‘utilization review’ methods to slow coverage/payment.” Exs. 18, 19.

127. As Biogen forecasted, FDA approved Aducanumab with a broad label (much broader than the trial population), CMS initiated a national coverage analysis, and MACs slowed/held claims. Instead of smoothing out MAC payment barriers as Vounatsos was prepared to ask, CMS had instead erected new ones.

128. In fact, Manquin had learned on June 25, 2021 from members of his MA&R team that a medical director at WPS (a MAC covering Michigan, Indiana, Missouri, Iowa, Nebraska, and Kansas) had stated, “Right now [Aduhelm] is up in the air. The CMDs [Chief Medical Directors] (of all the MACs) have been asked to not comment on this drug. CMS is working on deciding on how it should be covered and priced, *if at all*.” Ex. 20 (emphasis added).

129. Accordingly, Vounatsos and Alaimo misled investors that MACs and Regional Medicare Advantage plans “will provide coverage” for Aduhelm during the NCD analysis period when, in fact, they knew, or recklessly disregarded facts to the contrary.

G. The Market Slowly Learned that Obstacles to Commercializing Aduhelm, Which Has Been Concealed by Defendants’ Misrepresentations and Omissions, Meant that Aduhelm Would Not Be a Blockbuster Drug

1. Investors Learn on June 24 that Medicare Coverage Is Not Automatic and Biogen Was Considering Lowering Aduhelm’ Price

130. A growing chorus of stakeholders publicly objected to Aduhelm’s price tag, including, on June 12, 2021, the Alzheimer’s Association—a key advocacy group—released a statement deeming Biogen’s pricing of Aduhelm at \$56,000 a year as “simply unacceptable.”

131. But beginning in the afternoon of June 23, 2021, and continuing through June 24, 2021, persons in a position to directly influence CMS’s decision whether to take regulatory action voiced their concerns over Aduhelm’s price and advocated for CMS to use available tools of regulatory review to assess coverage for Aduhelm.

132. On June 23, 2021, United States Senator Bernie Sanders (VT) tweeted his objections to the high price of Aduhelm at 2:24 PM:

“[@SenSanders:] No. There’s absolutely no way Biogen should be allowed to charge patients \$56,000 for the new Alzheimer’s drug – costing Medicare up to \$29 billion a year. We must take on the greed of the pharmaceutical industry.”

133. Also midday on June 23, 2021, Biogen issued a press release attempting to address widespread scrutiny over, among other things, “the price of ADUHELM, impact on healthcare budget and patient access.” Biogen committed to “stand[ing] ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments shares or out-of-pocket expense for patients treated with ADUHELM.” Bloomberg Business News, in an article with a headline “Biogen Expects Slow Alzheimer’s Drug Uptake, May Reset Price” reported that “[t]he disclosure in a company statement Wednesday is a signal that the drug maker wants to tamp down the outcry over the treatment’s potential cost to the U.S. health-care system. The company

said it set the price based on the impact of the treatment and assumptions about how many people would take it. If those turn out to be wrong, [Biogen] stand[s] ready to work with public and private payers to address pricing . . .”

134. After the stock market closed on June 23, 2021, The Boston Globe reported that the CEO of Point32Health (an insurer formed by the merger of 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. The Globe article also reported that industry experts have said CMS may be asked to conduct an NCD.

135. Also, after market close on June 23, 2021, STAT+ reported that United States Senators Elizabeth Warren (MA) and Bill Cassidy (LA) had written a joint letter to the Senate Finance Committee asking the Committee to “take a deeper look at how Biogen’s controversial and pricey new Alzheimer’s drug, Aduhelm, will affect the Medicare program.” According to STAT+, the senators’ letter warned that “the size of the patient population eligible for Aduhelm, coupled with its high price, could lead to potentially catastrophic impacts on Medicare.” Further, the letter noted that ““FDA approval does not guarantee Medicare coverage.”

136. On the morning of June 24, 2021, before the start of trading, Senator Cassidy published a press release on his website containing the letter he and Senator Warren had sent to the Senate Finance Committee the prior night.:

Notably, FDA approval does not guarantee Medicare coverage, and so the program will need to answer an enormous question: should it cover a new and expensive Alzheimer’s medication, and if so, how? Medicare coverage is limited to items and services that are considered ‘reasonable and necessary’ for the diagnosis or treatment of an illness or injury, fit within the scope of a benefit category, and are not otherwise specifically excluded from coverage. The Centers for Medicare and Medicaid Services (CMS) has a number of tools to define the scope of coverage within those bounds in a manner that might – or might not – refine its broad label to limit the types of patients or scenarios in which it may be used. The agency may

grapple with questions about whether and how to identify the patients most likely to benefit from the drug and respond to differing opinions in the scientific community regarding its efficacy. CMS may also need to make decisions about coverage for potential ancillary services like amyloid PET scans. CMS might address these issues under its current authorities through the issuance of a national coverage determination, which could authorize coverage without restriction, limit coverage, or delay full coverage pending collection of more evidence. It might also be prudent for Congress to make policy changes to enable Medicare to move towards value-based payment arrangements, which directly connect prescription drug pricing to clinical effectiveness. [Emphasis added.]

Bloomberg, Endpoints News, and The Hill published coverage of the Senators' letter that morning.

137. Midday on June 24, 2021, during an interview with a STAT+ reporter livestreamed on YouTube, Department of Health and Human Services Secretary Xavier Becerra said, "Whether or not that drug [Aduhelm] will be covered by Medicare and Medicaid is an outstanding question, something HHS will have to deal with. We're going to be making some pretty heady decisions about how it's treated, if it will be reimbursed, how much, and so forth. So stay tuned."

138. Rachel Cohrs Zhang, Chief Washington Correspondent for STAT+ posted on X (the platform formerly known as Twitter) about Secretary Becerra's statement.

139. Biogen's stock price fell from its June 23, 2021 closing price of \$371.90 per share to close at \$349.16 per share on June 24, 2021 a statistically significant -7.23% decline, or \$25.93 per share.

2. CMS Announces the Opening of an NCD on July 12, 2021

140. On July 12, 2021, CMS announced the beginning of a NCD analysis that would examine whether, and under what circumstances, Medicare would provide coverage for monoclonal antibodies, i.e., treatments such as Aduhelm.

141. Biogen's stock price did not decline, and instead rose, in reaction to CMS' announcement as stock market analysts viewed the NCD as a positive for Biogen and continued to expect that CMS would provide for coverage of Aduhelm.

142. In reaction to the CMS announcement, Guggenheim analyst Yatin Suneja viewed the coverage determination as positive for Biogen: “Net-net, while this [NCD analysis] was expected by our experts, it comes earlier than our previous expectations, which is a boon for [Biogen] as the majority of potential Adu[helm] patients are covered by Medicare.”

143. Jefferies issued a report on July 12, 2021 regarding the NCD, stating “[t]his was mostly expected and positive in our view.... We think CMS will ultimately reimburse for the appropriate mild AD population (like the new label), allowing the drug to move forward with greater uptake and progress and [Biogen’s] stock to move higher as these pieces come together and overhangs are removed.” Jefferies continued its Buy rating on the stock, with a target price of \$500.

144. Guggenheim issued a Flash Note on July 12, 2021 commenting on the commencement of an NCD analysis by CMS stating: “there was some debate on whether an NCD will get triggered in this case, and we view today’s news as positive....” (Emphasis omitted). Guggenheim continued that “today’s news is a welcome advancement.... Net-net, while this decision was expected by our experts, it comes earlier than our previous expectations, which is a boon for [Biogen] as the majority of potential [Aduhelm] users are covered by Medicare.”

145. Truist issued a report on July 12, 2021, rating Biogen a BUY with a price target of \$647 noting the NCD “is a good thing for [Biogen] . . . we believe that the opening of the NCD is an important step towards reimbursement for Aduhelm.”

146. UBS issued a research report on July 13, 2021 discussing the NCD which it wrote had “been our baseline expectation.” It continued that its “payer/DC [expert] diligence suggests denial of coverage is highly unlikely, with ‘coverage with appropriateness,’ seeming like the most likely outcome for Aduhelm.” UBS continued its Buy rating and price target of \$475 per share.

147. Also on July 13, 2021, Guggenheim analyst Yatin Suneja wrote that Aduhelm was likely to benefit from an NCD and reiterated his buy recommendation on the stock.

148. During an earnings call before the market opened on July 15, 2021, the CEO of UnitedHealth Group—the largest private insurer in the United States and the largest Medicare Advantage plan administrator—announced it was waiting for the result of CMS’s NCD before defining its own policies around coverage for Aduhelm. Bloomberg Business News, which noted that “[c]ommercial success for Biogen hinges on whether doctors will prescribe it and insurers and government programs will reimburse for it,” reported that Biogen shares dropped 5% on the news.

149. The same day, Truist securities referenced UnitedHealth’s announcement in a research report with the headline “Commercial plans not likely to reimburse until NCD – near-term focus on MACs” and noted that it expected most commercial insurers not to provide coverage for Aduhelm during the pendency of the NCD.

150. Reuters also reported on July 15, in an article titled “Biogen Alzheimer’s Drug Hits Roadblocks with Some Hospitals, Insurers,” that “Humana, the second largest provider of Medicare Advantage plans, also said it has not finalized coverage for Aduhelm as it awaits guidance from [CMS].” Reuters added that “[s]everal Blue Cross Blue Shield health insurance plans, including those in Michigan, North Carolina, and Pennsylvania, have said there is insufficient evidence of Aduhelm’s benefit for patients and they will not provide coverage for the drug.” The Blue plans characterized Aduhelm as “experimental and investigational”—a term explicitly at odds with CMS’s “reasonable and necessary” standard for coverage.

151. Biogen’s stock price on July 15, 2021 fell by \$23.90 per share to close at \$328.16 per share, a 6.8% drop.

152. After market close on July 15, 2021, Dr. Mark McClellan—a former FDA Commissioner and CMS Administrator—spoke at a livestreamed ICER/CTAF conference on Alzheimer’s Disease. He said that MACs “will likely push back on covering Aduhelm until an NCD has been issued” and the Medicare coverage of Aduhelm “is going to be pretty limited at least until” after the NCD is decided, so we are “not going to see very big numbers in the near term.” And he explained that “most MACs are ‘saying no’ because they are likely waiting for the national decision.” These statements were also covered in analyst reports issued that day by UBS, RBC, and Mizuho.

153. Mizuho analyst Salim Syed wrote in a research report dated July 15, 2021, that “Mark McClellan, a former CMS administrator, just finished speaking at today’s ICER meeting. He noted that Aduhelm access ‘is going to be pretty limited at least until [after the NCD was decided]’ and that we are ‘not going to see very big numbers in the near term.’” Syed reported that McClellan also expressed his belief “that most local coverage is ‘saying no’ because they themselves are likely waiting for the national [coverage] decision.”

154. Biogen’s stock price opened on July 16, 2021 at \$323.97, down from the previous day’s close of \$328.16, and dropped as low as \$323.00 per share before closing at \$324.62.

155. On July 22, 2021, Biogen held a conference call to discuss the Company’s financial results from the second quarter of 2021. Biogen beat market expectations for Q2 2021 earnings and its stock price rose 1.6% in pre-market trading in response. On the earnings call, Defendants made new misleading statements about Medicare coverage by MACs during the pending NCD.

3. The Market Learns on September 9, 2021 the Aduhelm Launch Is Slow Due to Concerns Regarding Reimbursement

156. On September 9, 2021, Vounatsos and Alaimo attended a Morgan Stanley Global Healthcare Conference (“Morgan Stanley Conference”) where Vounatsos admitted that the

“launch” was “slower than we initially anticipated.” Alaimo explained that among the “main challenges ... contributing to this gradual launch” was the “higher-than-expected level of uncertainty with respect to reimbursement... compounded by the [NCD] analysis by CMS” which “has obviously been compounded by the National Coverage Determination analysis by CMS.” Alaimo added, “We believe the majority of sites are waiting for clarity on reimbursement, including the outcome of the NCD, which could be another 7 months, according to the CMS announcement.”

157. Bloomberg Business News reported at 9:53 am on September 9, 2021, that “Biogen falls 6.4% in Thursday trading as management gives a presentation at a Morgan Stanley Global Healthcare Conference. CEO Michel Vounatsos and other members of management are answering questions about the launch and reimbursement issues with its controversial Alzheimer’s disease drug, Aduhelm.” At 12:42 pm the same day, Bloomberg reported, “[Biogen] stock fell for a seventh day on Thursday [September 9], solidifying roughly \$7 billion loss after management said the introduction of Aduhelm was facing several challenges.” The report continued: “The company’s focus will not be on short-term revenue, but on Aduhelm data, infrastructure and reimbursement he said. The stock extended drop after his admission, hitting the lowest since June.” And finally after market close, at 4:20pm, Bloomberg updated its reporting on the day to conclude that “Biogen Inc. notched its longest losing streak in over two years after the biotech company confirmed Wall Street fears that the rollout of its Alzheimer’s drug wasn’t going as well as hoped.”

158. Biogen’s stock opened at \$322 per share on September 9, 2021, and immediately began to fall as reports of Vounatsos’ statements were reported to the market. Biogen’s stock price closed at \$300.15 per share, a 6.7% decline.

159. Stock market analysts noted the problems Biogen was facing. Guggenheim's Suneja wrote that at the Morgan Stanley Conference Biogen management admitted it was "experiencing 'near-term challenges' in getting [Aduhelm] to patients."

160. A *FirstWord Pharma* article published on September 9, 2021, noted that "Aduhelm has faced hesitancy from some hospitals and insurers amid concerns over its efficacy and \$56,000 annual cost." The article stated that RBC analyst Brian Abrahams noted that Biogen's stock is "now starting to reflect much more pessimism about Aduhelm uptake and competitive impact."

161. Morgan Stanley, in a research report dated September 9, 2021, noted that there was "[h]igher than expected reimbursement uncertainty" with the "majority of sites waiting for clarity on the NCD prior to infusing Aduhelm."

162. On December 20, 2021, Biogen announced it was cutting the price of Aduhelm in half, to \$28,200.

163. On January 11, 2022, after the close of stock trading, CMS announced their draft decision on reimbursement for Aduhelm. CMS 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, CMS proposed limiting reimbursement to clinical trials in a hospital-based outpatient setting. The restrictions meant Medicare reimbursement would only be available to a small patient population, and with many hospitals refusing to provide Aduhelm at all, where those clinical trials could take place was further limited. Private insurance providers often follow the guidance of CMS in their own coverage decisions.

164. Biogen's stock price plunged on the news, closing at \$225.34 per share on January 12, 2021, down from the closing price of \$241.52 per share on January 11, 2022.

165. On February 4, 2022, Biogen announced both the U.S. Federal Trade Commission, and SEC were investigating the Company over its claims regarding "healthcare sites," the FDA's approval of Aduhelm, and the marketing of the treatment.

166. On March 13, 2022, after the conclusion of the Class Period, and over 5 months after Vounatsos had promised providers would have access to peer-reviewed data on Aduhelm, Biogen finally published the results of their Phase III studies in a minor academic journal.

167. On May 3, 2022, Biogen announced that Vounatsos would be stepping down as CEO of Biogen once a replacement candidate was found. At the same time, Biogen announced it was functionally ending its attempts to commercialize Aduhelm, terminating all employees responsible for sales and marketing of the treatment. The Wall Street Journal reported that "[t]he company will substantially eliminate the sales infrastructure it built to support Aduhelm's launch, including employees to promote the drugs to doctors and provide logistical assistance for navigating the complex process of administering it to patients" noting that "the cuts will comprise the bulk of an estimate \$500 million in annual savings that the company is targeting." In describing the end of the program, the Wall Street Journal stated "[s]ome analysts had expected Aduhelm would help transform Biogen, diversifying its product suite" but noted "doctors disagreed about the drug's effectiveness, utility and cost, which was initially set at \$56,000 annually before being slashed in half in response to criticism."

H. Class Action Allegations

168. Lead Plaintiff bring this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a Class consisting of all those who purchased or otherwise acquired the

common stock of Biogen between June 7, 2021, and September 8, 2021, inclusive, and who were damaged thereby (the “Class”). Excluded from the Class are Defendants, the officers and directors of Biogen at all relevant times, members of their immediate families and their legal representatives, heirs, agents, affiliates, successors or assigns, Defendants’ liability insurance carriers, and any affiliates or subsidiaries thereof, and any entity in which Defendants or their immediate families have or had a controlling interest.

169. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Biogen shares were actively traded on the NASDAQ Stock Market. As of March 31, 2021, Biogen had over 145 million shares of common stock outstanding, owned by thousands of investors. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believe that there are thousands of members of the proposed Class. Class members who purchased Biogen common stock may be identified from records maintained by Biogen or its transfer agent(s) and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

170. Lead Plaintiff’s claims are typical of Class members’ claims, as all members of the Class were similarly affected by Defendants’ wrongful conduct in violation of federal laws as complained of herein.

171. Lead Plaintiff will fairly and adequately protect Class members’ interests and have retained competent counsel experienced in class actions and securities litigation.

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

- a. whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;
- b. whether the Defendants made statements to the investing public during the Class Period that were false, misleading, or omitted material facts;
- c. whether Defendants acted with scienter; and
- d. whether Lead Plaintiff and the Class were damaged and the proper measure of damages.

173. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation make it impossible for such members to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

I. Fraud On the Market

174. Lead 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 an efficient market;
 - d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock, and;
 - e. Lead 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.

175. At all relevant times, the market for the Company's stock was efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; (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; and (iii) the Company is regularly followed by stock market analysts who publish information regarding the Company. Lead 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.

176. At all relevant times, the market for Biogen's common stock was efficient for the following reasons, among others:

- a. Biogen's stock met the requirements for listing, and was listed and actively traded on the NASDAQ Stock Market, a highly efficient and automated market;
- b. As a regulated issuer, Biogen filed periodic reports with the SEC and the NASDAQ Stock Market;
- c. Biogen 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

- d. Biogen was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public marketplace.

177. As a result of the foregoing, the market for Biogen's common stock reasonably promptly digested current information regarding Biogen from all publicly available sources and reflected such information in the price of Biogen's common stock. All purchasers of Biogen common stock during the Class Period suffered similar injury through their purchase of Biogen common stock at artificially inflated prices, and a presumption of reliance applies.

178. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose.

J. No Safe Harbor

179. The statutory safe harbor or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this Complaint. None of the statements complained of herein was a forward-looking statement. Rather, the statements were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including statements about among other things, (i) whether Medicare coverage for Aduhelm was "automatic" upon FDA approval; (ii) whether Biogen engaged or consulted with payers in determining Aduhelm's annual price; and (iii) that MACs and MA plans "will provide coverage" for Aduhelm during the pendency of the NCD.

180. To the extent that any of the false or misleading statements alleged herein can be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As set forth above in detail, then-existing facts contradicted Defendants' statements regarding, among other things, (i) FDA approval did not equate to automatic coverage for Aduhelm; (ii) Biogen did not engage or consult with payers on the price of Aduhelm; and (iii) MACs and MA plans were pushing back on, and implementing administrative barriers to paying claims for treatment with Aduhelm after FDA approval.

181. To the extent that the statutory safe harbor does not apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those statements was made, the particular speaker knew that the particular forward-looking statement was false, and the false forward-looking statement was authorized and approved by an executive officer of Biogen who knew that the statement was false when made.

K. Loss Causation

182. The fraud described herein was the proximate cause of declines in Biogen's stock price and resulting losses suffered by the Class. Defendants' materially false and misleading statements and omissions of material facts artificially inflated and/or maintained the price of Biogen's stock. The artificial inflation in Biogen's stock price was removed through a series of partial disclosures concerning the facts concealed and/or misrepresented by the misstatements and omissions, described below. These partial disclosures reduced the amount of inflation in the price of Biogen's publicly traded stock, causing economic injury to Plaintiffs and other members of the Class.

183. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶74-76, 99-101, and 118-119 had the intended effect and caused Biogen stock to trade at artificially inflated prices during the Class Period. Taken together, Defendants' misleading statements and omissions of material fact were calculated to convey that Aduhelm would be a blockbuster drug and be a commercial success following the FDA's approval of the treatment.

184. The statements, articles, and events identified herein at ¶¶130-167 in Section G, "G. The Market Slowly Learned that Obstacles to Commercializing Aduhelm, Which Has Been Concealed by Defendants' Misrepresentations and Omissions, Meant that Aduhelm Would Not Be a Blockbuster Drug" served as corrective disclosures. As investors digested the partial corrective disclosures, the market began to learn that there were impediments to reimbursement for Aduhelm and the launch of Aduhelm would not produce the revenues anticipated by investors.

185. On June 23, 2021, Biogen issued a press release attempting to placate widespread scrutiny over, among other things, "the price of ADUHELM, impact on healthcare budget and patient access." Biogen committed to "not ... increasing the price of ADUHELM in the first four years following launch," and said, "[w]e stand ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments shares or out-of-pocket expenses for patients treated with ADUHELM." Bloomberg Business News reported that on the press release in an article, "Biogen Expects Slow Alzheimer's Drug Uptake, May Reset Price." The Bloomberg story reported that "[t]he disclosure in a company statement Wednesday is a signal that the drug maker wants to tamp down the outcry over the treatment's potential cost to the U.S. health-care system. The company said it set the price based on the impact of the treatment and assumptions about how many people would take it. If those turn out to be wrong, [Biogen] stand[s] ready to work with public and private payers to address pricing . . ."

186. Also on June 23, 2021, United States Senator Bernie Sanders (VT) tweeted his objections to the high price of Aduhelm at 2:24 PM:

“[@SenSanders:] No. There’s absolutely no way Biogen should be allowed to charge patients \$56,000 for the new Alzheimer’s drug – costing Medicare up to \$29 billion a year. We must take on the greed of the pharmaceutical industry.”

187. After the stock market closed on June 23, 2021, The Boston Globe reported that the CEO of Point32Health (an insurer formed by the merger of 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. The Globe article also reported that industry experts have said CMS may be asked to conduct an NCD.

188. Also after market close on June 23, 2021, STAT+ reported that United States Senators Elizabeth Warren (MA) and Bill Cassidy (LA) had written a joint letter to the Senate Finance Committee asking the Committee to “take a deeper look at how Biogen’s controversial and pricey new Alzheimer’s drug, Aduhelm, will affect the Medicare program.” According to STAT+, the senators’ letter warned that “the size of the patient population eligible for Aduhelm, coupled with its high price, could lead to potentially catastrophic impacts on Medicare.” Further, the letter noted that “FDA approval does not guarantee Medicare coverage.”

189. On the morning on June 24, 2021, before the start of trading, Senator Cassidy published a press release on his website containing the letter he and Senator Warren had sent to the Senate Finance Committee the prior night:

Notably, FDA approval does not guarantee Medicare coverage, and so the program will need to answer an enormous question: should it cover a new and expensive Alzheimer’s medication, and if so, how? Medicare coverage is limited to items and services that are considered ‘reasonable and necessary’ for the diagnosis or treatment of an illness or injury, fit within the scope of a benefit category, and are not otherwise specifically excluded from coverage. The Centers for Medicare and Medicaid Services (CMS)

has a number of tools to define the scope of coverage within those bounds in a manner that might – or might not – refine its broad label to limit the types of patients or scenarios in which it may be used. The agency may grapple with questions about whether and how to identify the patients most likely to benefit from the drug and respond to differing opinions in the scientific community regarding its efficacy. CMS may also need to make decisions about coverage for potential ancillary services like amyloid PET scans. CMS might address these issues under its current authorities through the issuance of a national coverage determination, which could authorize coverage without restriction, limit coverage, or delay full coverage pending collection of more evidence. It might also be prudent for Congress to make policy changes to enable Medicare to move towards value-based payment arrangements, which directly connect prescription drug pricing to clinical effectiveness.

Bloomberg, Endpoints News, and The Hill quickly published coverage of the Senators' letter that morning.

190. Midday on June 24, 2021, during an interview with a STAT+ reporter livestreamed on YouTube, Department of Health and Human Services Secretary Xavier Becerra said, “Whether or not that drug [Aduhelm] will be covered by Medicare and Medicaid is an outstanding question, something HHS will have to deal with. We’re going to be making some pretty heady decisions about how it’s treated, if it will be reimbursed, how much, and so forth. So stay tuned.”

191. Rachel Cohrs Zhang, Chief Washington Correspondent for STAT+ posted on X (the platform formerly known as Twitter) about Secretary Becerra’s statement.

192. On June 24, 2021, Biogen’s stock price opened at \$349.96 per share, down from its closing price of \$371.90 on June 23, 2021. It closed at \$349.16 on June 24, 2021. This decline, which was statistically significant at the 99% confidence level, caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen’s stock price was partially removed.

193. On the morning of June 28, 2021, the Wall Street Journal reported that Medicare may restrict access to Aduhelm to limit the cost to Medicare. Biogen’s share price closed at

\$340.27 on June 28, 2021. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

194. Between June 21, 2021, and June 28, 2021, Biogen's stock price fell by \$48.17 per share, or 12.5% as news problems with Aduhelm began to leak out. This overall decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

195. During an earnings call before the market opened on July 15, 2021, the CEO of UnitedHealth Group—the largest private insurer in the United States and a Medicare Advantage plan administrator—announced it was waiting for the result of CMS's NCD before defining its own policies around coverage for Aduhelm. Bloomberg Business News, which reported that UnitedHealth was seeking “guidance from Medicare” in evaluating “how it will cover Aduhelm,” also noted that “[c]ommercial success for Biogen hinges on whether doctors will prescribe it and insurers and government programs will reimburse for it.” Bloomberg Business News reported that Biogen shares dropped 5% on the news. Later that day, Truist securities issued a research report referencing UnitedHealth's announcement and noted that it expected most commercial insurers not to provide coverage for Aduhelm during the pendency of the NCD.

196. Reuters also reported that day, in an article titled “Biogen Alzheimer's Drug Hits Roadblocks with Some Hospitals, Insurers,” that “Humana, the second largest provider of Medicare Advantage plans, also said it has not finalized coverage for Aduhelm as it awaits guidance from [CMS].” Reuters added that “[s]everal Blue Cross Blue Shield health insurance plans, including those in Michigan, North Carolina, and Pennsylvania, have said there is insufficient evidence of Aduhelm's benefit for patients and they will not provide coverage for the

drug.” The Blue plans characterized Aduhelm as “experimental and investigational”—a term explicitly at odds with CMS’s “reasonable and necessary” standard for coverage.

197. Biogen’s stock price on July 15, 2021 fell by \$23.90 per share to close at \$328.16 per share. This decline, which was statistically significant at the 99% confidence level, caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen’s stock price was partially removed.

198. After market close on July 15, 2021, Dr. Mark McClellan—a former FDA Commissioner and CMS Administrator—spoke at a livestreamed ICER/CTAF conference on Alzheimer’s Disease. He said that MACs “will likely push back on covering Aduhelm until an NCD has been issued” and the Medicare coverage of Aduhelm “is going to be pretty limited at least until” after the NCD is decided, so we are “not going to see very big numbers in the near term.” And he explained that “most MACs are ‘saying no’ because they are likely waiting for the national decision.” These statements were also covered in analyst reports issued that day by UBS, RBC, and Mizuho.

199. Biogen’s stock price on July 16, 2021 opened at \$323.97, down from the previous day’s close of \$328.16, and dropped as low as \$323.00 per share before closing at \$324.62.

200. On September 9, 2021, Vounatsos and Alaimo attended a Morgan Stanley Global Healthcare Conference (“Morgan Stanley Conference”) where Vounatsos admitted that the “launch” was “slower” than anticipated. Alaimo explained that one “main challenge is a higher-than-expected level of uncertainty with respect to reimbursement,” which “has obviously been compounded by the National Coverage Determination analysis by CMS.” Said Alaimo, “We believe the majority of sites are waiting for clarity on reimbursement, including the outcome of the NCD, which could be another 7 months, according to the CMS announcement.”

201. A *First World Pharma* article published on September 9, 2021, noted that “Aduhelm has faced hesitancy from some hospitals and insurers amid concerns over its efficacy and \$56,000 annual cost.” The article stated that RBC analyst Brian Abrahams noted that Biogen’s stock “is already now starting to reflect much more pessimism about Aduhelm uptake and competitive impact.” Stock market analysts noted that day that most commercial insurers would likely not cover Aduhelm until after CMS decided the NCD. Morgan Stanley noted that there was “[h]igher than expected reimbursement uncertainty” with the “majority of sites waiting for clarity on the NCD prior to infusing Aduhelm.”

202. Biogen’s stock opened at \$321.55 per share on September 9, 2021, and immediately began to fall as reports of Vounatsos’ statements were reported to the market. Biogen’s stock price closed at \$300.15 per share, a 6.7% decline. This decline, which was statistically significant at the 99% confidence level, caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen’s stock price was partially removed.

203. On January 11, 2022, after the close of stock trading, CMS released its draft opinion, limiting Medicare reimbursement for Aduhelm to only coverage with evidence development—i.e., patients enrolled in approved clinical trials. This announcement fully revealed the truth that that Medicare coverage was not automatically presumed following FDA approval, and was the final materialization of the risks concealed by Defendants’ false and misleading statements about Medicare coverage and having engaged with payers on price. On January 12, 2022, Biogen’s stock price fell by \$16.18 per share to close at \$225.34 per share. This decline, which was statistically significant at the 99% confidence level, caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen’s stock price was finally removed in full.

204. The declines in Biogen's stock price were a direct and proximate result of the fraud described herein. The timing and magnitude of Biogen's stock-price declines negate any inference that the economic losses and damages suffered by Lead Plaintiff and the other members of the Class were caused by changed market conditions, macroeconomic factors, or Biogen-specific facts unrelated to Defendants' fraudulent conduct.

V. COUNT I

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

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

206. This Count is asserted on behalf of all members of the Class against Defendant Biogen and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

207. During the Class Period, Defendants made, disseminated, or approved the false and misleading statements specified above, which they knew were, or deliberately disregarded as, 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.

208. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiff and other

members of the Class in connection with their purchases of Biogen common stock during the Class Period.

209. Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiff and the Class; made various untrue and/or misleading statements of material facts and omitted to state material facts when necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with deliberate recklessness; and employed devices and artifices to defraud in connection with the purchase and sale of Biogen common stock which were intended to and did:

(a) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, Medicare's "automatically presumed" requirement to pay for treatment of Aduhelm; Biogen's engagement and consultation with payers on the price of Aduhelm; and whether MACs and Medicare Advantage plans would pay for Aduhelm during the pendency of the NCD;

(b) artificially inflate and maintain the market price of Biogen common stock; and

(c) cause Lead Plaintiff and other members of the Class to purchase Biogen common stock at artificially inflated prices and suffer losses when the true facts became known.

210. Defendant Biogen and the Individual Defendants are liable for all the materially false and misleading statements and for omitting to reveal material facts during the Class Period as alleged above.

211. As alleged herein, Defendants acted with scienter throughout the Class Period, in that they acted either with intent to deceive, manipulate or defraud, or with deliberate recklessness.

They misrepresentations and omissions of material facts set forth herein, which presented a danger of misleading buyers and sellers of Biogen stock, were either known to the Defendants or so obvious that Defendants should have been aware of them.

212. Lead Plaintiff and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Biogen common stock, which inflation was removed from its price when the true facts became known. Lead Plaintiff and the Class would not have purchased Biogen common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by Defendants' materially misleading statements.

213. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the material misstatements and omissions alleged herein in connection with their purchases of Biogen common stock during the Class Period.

VI. COUNT II

For Violation of § 20(a) of the Exchange Act (Against the Individual Defendants)

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

215. This count is asserted on behalf of all members of the Class against the Individual Defendants for violations of § 20(A) of the Exchange Act, 15 U.S.C. §78t(a).

216. By reason of their high-level positions of control and authority as the Company's most senior officers, the Individual Defendants had the authority to influence and control, and did influence and control, the decision-making and the activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. The Individual

Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Biogen during the Class Period, thereby causing the dissemination of the materially false or misleading statements and omissions of material facts as alleged herein. The Individual Defendants were provided with, or had unlimited access to, copies of the Company's press releases, public filings, and other statements alleged by Lead 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 to cause the statements to be corrected.

217. Each of the Individual Defendants spoke to investors on behalf of the Company during the Class Period. Therefore, each of the Individual Defendants was able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Biogen during the Class Period, thereby causing the dissemination of the materially false or misleading statements and omissions of material facts as alleged herein.

218. As set forth above, Biogen violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint.

219. By virtue of their positions as controlling persons of Biogen and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as, the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiff and the other members of the Class who purchased or otherwise acquired Biogen common stock. As detailed above, during the respective times, these Individual Defendants served as officers and/or directors of Biogen.

220. As a direct and proximate result of the Individual Defendants' conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of Biogen common stock.

PRAYER FOR RELIEF

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

- (a) Declaring the action to be a proper class action under Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein;
- (b) Awarding all damages available under the Securities Exchange Act in favor of Lead Plaintiff and the other members of the Class against all Defendants, jointly and severally, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;
- (c) Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and experts' fees and other costs and disbursements; and
- (d) Awarding such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

[SIGNATURE ON NEXT PAGE]

Dated: February 18, 2025

Respectfully submitted,

/s/ Jeffrey C. Block

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