UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OKLAHOMA FIREFIGHTERS PENSION AND RETIREMENT SYSTEM, Plaintiff, v. BIOGEN INC., MICHEL VOUNATSOS, ALFRED SANDROCK, AND ALISHA ALAIMO, Defendants.	Civil Action No. 1:22-cv-10200-WGY CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS Jury Trial Demanded

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1. Lead Plaintiff, Oklahoma Firefighters Pension and Retirement System ("Lead Plaintiff"), alleges the following based upon 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) transcripts of Biogen's earnings and other conference calls with investors and analysts; (vi) publicly available presentations, press releases, and interviews by Biogen and its employees; (vii) economic analyses of the movement and pricing of Biogen's publicly traded common stock; and (viii) interviews with former employees ("FEs") of Biogen.

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 believes that substantial additional evidentiary support will exist for the Complaint's allegations after a reasonable opportunity for discovery, including access to the materials that Defendants and third parties have produced to, among others, the U.S. Food and Drug Administration ("FDA"), the U.S. Securities and Exchange Commission ("SEC"), the Federal Trade Commission ("FTC"), the U.S. House of Representatives Committee on Oversight and Reform, other federal agencies, and third-parties.

3. This matter is a securities class action brought against Biogen and three of its executives (collectively "Defendants") for false and misleading statements made to investors in

connection with the Company's rollout of aducanumab, branded as Aduhelm[1], a monoclonal antibody treatment for Alzheimer's disease. The putative class is comprised of investors who purchased or otherwise acquired Biogen stock between June 7, 2021, and January 11, 2022, 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 its new drug, Aduhelm through five categories of false and misleading statements concerning the following: (i) the number of sites ready, willing, and able to administer Aduhelm immediately after approval; (ii) the significance of logistical constraints on diagnosing patients; (iii) the degree to which Medicare's coverage of the treatment was independent of the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm at a premium price point, or, indeed, at any price point absent peer-reviewed data supporting a determination of the treatment's clinical effectiveness; and (v) the Veterans Health Administration (the "VA" or "Veterans Administration") willingness and capacity to cover and administer Aduhelm for its beneficiaries. In addition to these categories of false and misleading statements, throughout the Class Period, Defendants misled investors as to their irregular interactions with the FDA prior to Aduhelm's approval, which later became the subject of investigations by the Inspector General of the Department of Health and Human Services, and Congress, and contributed to a significant portion

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

of the medical community questioning Aduhelm's efficacy, driving provider hesitancy to prescribe it. Fueled by Defendants false and misleading statements, Biogen's stock price skyrocketed following the FDA's approval of Aduhelm, increasing from $286.14 per share to close at $395.85 on June 7, 2021, a $14.6 billion one day price increase in the Company's market capitalization. By the end of the Class Period, after the market came to learn that there was a fraction of the sites actually ready to treat patients, that sales of Aduhelm were significantly slower than expected, that Medicare would not cover most patients, and that most third-party payers balked at Adhulem's hefty price tag, Biogen's stock price fell to $225 per share, well-below its pre-FDA approval price, removing all the inflation in Biogen's stock.

I. INTRODUCTION

5. 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.

6. 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.

7. 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 CIMB, wrote that Aduhelm "may have saved the company actually given the myriad franchise and competitive risk throughout the rest of their commercial businesses . . .."

8. In March 2019, Biogen, in consultation with a group of outside advisors brought in to conduct a "futility analysis," determined that there was insufficient evidence of a clinical benefit in patients to justify the submission of Aduhelm for FDA approval. Biogen discontinued Aduhelm's Phase III trials and announced the disappointing results to investors on March 21, 2019. Biogen's CEO, Defendant Vounatsos, referred to the failure as "evidence of the complexity of treating Alzheimer's Disease and the need to further advance knowledge of neuroscience." On this news Biogen stock plummeted almost 30%, from $320.59 to $226.88 per share.

9. Some of Biogen's executives were not prepared to accept this outcome. According to news reports, as early as April 2019, Biogen's Chief Medical Officer Alfred Sandrock decided to reach out to the FDA to determine if there was any path forward for approval, notwithstanding the results of Aduhelm's Phase III trials. The head of the FDA's Division of Neuroscience, Billy Dunn, was a former colleague of Sandrock, and, allegedly, became an internal advocate at the FDA for Aduhelm's approval.

10. Internally, Biogen's lobbying campaign with the FDA was called "Project Onyx," and these efforts are presently the subject Congressional investigations, as well an investigation by the Office of the Inspector General of U.S. Health and Human Services. The SEC and FTC are also investigating Biogen in connection with Aduhelm's approval and marketing. Both STAT

News and the New York Times, in June and July 2021 respectively, wrote exposés on Biogen's irregular contacts with the FDA to get Aduhelm approved and thereafter, on July 9, 2021, the then Acting Commissioner of the FDA requested the Inspector General of the Department of Human Services to investigate how Aduhelm received FDA approval noting there was contact between the FDA and Biogen outside the normal course.

11. On October 22, 2019, merely half a year after announcing it would not submit Aduhelm for FDA approval, Biogen completely changed course and announced it would be submitting Aduhelm to the FDA for approval as a result of a "new analysis" of the data from the treatment's Phase III trials. Biogen completed the submission of Aduhelm for FDA approval in July 2020, and, looking ahead to the treatment's commercial rollout, announced that it had begun efforts to identify potential treatment sites across the country and engage with stakeholders to price the treatment.

12. Securing FDA approval for Aduhelm proved to be an uphill battle. On November 6, 2020, the FDA's Peripheral and Central Nervous System Drug Advisory Committee (the "PCNS Advisory Committee") unanimously recommended against approving Aduhelm to treat Alzheimer's disease, based largely on a lack of demonstrable clinical benefit. The Company was undeterred as Biogen was reportedly informed by Dunn that the FDA would approve Aduhelm. Indeed, by spring of 2021, Biogen had substantially ramped up its nationwide campaign to identify potential treatment sites and "educate" healthcare providers and other stakeholders about Aduhelm's benefits to prepare for Aduhelm's rollout following the FDA's anticipated approval of the treatment.

13. Before 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 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 analysts' 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."

14. On June 7, 2021, the FDA approved Aduhelm through its Accelerated Approval process for the treatment of Alzheimer's disease. In public statements the same day, Biogen announced it would price Aduhelm at approximately $56,000 per person, per year. That day, in various interviews, Vounatsos told investors that there were 900 sites ready to start treating patients and Biogen was ready to ship millions of doses of the treatment. Investors also knew from Vounatsos' prior statements that Biogen had done a "thorough engagement" on price with stakeholders, including private and public payers – a point he emphasized in interviews the same day. And investors knew from Vounatsos' prior statements that that at least 600 sites were ready to start treatment. Investors believed Aduhelm was primed to be a blockbuster drug for Biogen. Biogen's stock skyrocketed by over $100 per share, representing an increase in market capitalization of approximately $14.6 billion on June 7, 2021.

15. Stock market analysts reacted positively to the news. For example, CIMB's Seedhouse wrote "Upgrade to Market Perform; [wide-eyed emoji]; Bring on the ~$330B Market

Opportunity." Guggenheim's Yatin Suneja and Eddie Hickman wrote "[Biogen] – Adu Priced at $56k/Year vs. our $50k Est; [Biogen] Est 1-2MM Addressable Patients With Amyloid Pathology, Implying a $50-100B TAM." Analysts from BTIG wrote "We have probably been more positive on the chances for approval than consensus but fairly skeptical on commercialization due to possible scan requirements and the potential for serious [adverse effects]. . . . The three required. . . scans seem a moderate requirement relative to the numbers in most trials and could aid in the rollout."

16. The next day, June 8, 2021, in both press releases and during a conference call with investors, Defendants focused their comments on Aduhelm's commercial rollout – and made false and misleading statements about five topics: (i) the number of sites ready, willing and able to administer Aduhelm in the near-term; (ii) the significance of logistical constraints on diagnosing potential patients; (iii) the degree to which Medicare's coverage of the treatment was independent of the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm at a premium price-point, or, indeed, at any price-point absent peer-reviewed data supporting a determination of the treatment's clinical effectiveness; and (v) the VA's willingness and capacity to cover and administer Aduhelm for its beneficiaries. Defendants also omitted to reveal the unusual relationship between Biogen and the FDA that led to Accelerated Approval of Aduhelm. Among other reasons, as it became known during the Class Period, this unusual relationship contributed to skepticism among the medical community in deciding whether to prescribe Aduhelm to their patients and was one reason many members of the medical community decided to wait for Biogen to publish peer reviewed data before they would prescribe the treatment. These false and misleading statements and material omissions all created the picture that Aduhelm was ready to be administered in the United States at hundreds of sites, that pricing would not be an

obstacle, and that Medicare coverage after FDA approval was "automatic." Biogen's stock price rose again on June 8, 2021 to close at $406.14 per share.

17. First, Defendants statements that there were "900 sites ready to implement treatment with Aduhelm" in the United States at the time of FDA approval was false and materially misleading when made. Multiple former employees of Biogen have confirmed this claim was false and that the actual number of treatment sites ready, willing, and able to administer Aduhelm was, far lower, and that Biogen's executives either knew or recklessly disregarded the truth that the number of sites ready to administer Aduhelm was significantly lower than 900. Indeed, approximately 6 weeks later, Vounatsos admitted that of the 900 sites, only 325 were actually ready to treat as only 325 had completed an internal "pharmacy and therapeutics committee reviews" also called "P&T" - which required review of the FDA's approval of the drug, label, cost and whether the treatment would be covered by third-party payers – none of which could have occurred prior to June 7, 2021. By September 2021, Vounatsos and Alaimo admitted that only 50 sites were actually administering Aduhelm, .055% of the number investors were told were "ready to treat" on day one.

18. Second, Defendants mislead investors by downplaying the significance of logistical constraints on identifying the presence of amyloid beta in potential Aduhelm patients. Defendants stated that most physicians would want to determine the presence of amyloid beta in a patient before prescribing Aduhelm to treat that patient. There are two methods to test for amyloid beta in an individual: securing brain imaging via positron-emission tomography (a "PET scan") or a lumbar puncture via a spinal tap to test the cerebrospinal fluid (CSF) of the patient. Defendants acknowledged that PET scans were not covered by Medicare and were quite expensive, so most patients would not use a PET scan to test for amyloid beta. During the clinical trials, PET scans,

paid for by Biogen, were used to determine the presence of amyloid beta. As for CSFs, Defendants touted a partnership with Labcorp and Mayo Clinic Laboratories to test the cerebrospinal fluid of potential patients for evidence of amyloid beta, suggesting they had created a relatively simple pathway for patients to be tested for the presence of amyloid beta, which would lead to the patient being prescribed Aduhelm. Defendants omitted to reveal, however, that Biogen's sales force had encountered tremendous resistance, if not downright hostility, from doctors when they suggested CSF analysis as a means to test for amyloid beta. Many healthcare providers opposed referring elderly patients with dementia or Alzheimer's for a lumbar puncture, more commonly known as a spinal tap. A lumbar puncture was simply not an option for a significant portion of the population described by Defendants as potential Aduhelm patients, whether because of age, infirmity, other complicating health factors, or simply because of their healthcare provider's unwillingness to recommend a painful, exhausting, and sometimes dangerous procedure as a prerequisite to receiving a treatment of doubtful clinical benefit. Plus, many of the sites at which the lumbar puncture was required to be performed were reluctant to perform them as the reimbursement rates were quite low and the sites would make more money performing other procedures. Importantly, Biogen's former employees repeatedly emphasized these logistical and economic constraints during their evaluations of potential treatment sites. Defendants knew or recklessly disregarded the truth that there was a major bottleneck preventing most patients from even receiving a diagnosis sufficient to warrant them to begin receiving Aduhelm to treat dementia, cognitive decline, or Alzheimers disease.

19. Third, Defendants characterized Medicare's coverage of Aduhelm as "automatically presumed" following FDA approval – a point emphasized by several influential market analysts. These characterizations were false and misrepresented that Medicare coverage

was "automatically presumed" once the FDA approved Aduhelm. Ultimately, as described below, the U.S. Centers for Medicare and Medicaid Services ("CMS") engaged in a National Coverage Determination ("NCD") with respect to Aduhelm and eventually determined that Medicare coverage for Aduhelm would be limited to reimbursement for treatments administered to patients enrolled in CMS-approved randomized clinical trials. Coverage was not "automatic."

20. Fourth, Defendants misleadingly suggested that third-party payors had expressed support, approval, or, at a minimum, a willingness to accept Aduhelm's initial annual price point of $56,000 per patient. Defendants attributed their confidence in the treatment's pricing to "engagement" with both public and private "stakeholders, including clinical experts, health economics, policymakers and payers. . ." and claimed that the price "reflected the overall value the treatment" would bring to "patients, caregivers and society." In truth, many third-party payors balked at Aduhelm's price point.

21. Defendants also omitted to reveal that many healthcare providers were unwilling to provide the treatment at any price until they could see peer-reviewed data supporting the treatment's clinical benefit – a problem repeatedly identified to Biogen's executives according to former employees. Defendants Vounatsos and Alaimo admitted as much at a September 9, 2021, Morgan Stanley HealthCare Conference. Plus, Bloomberg news published a survey on November 18, 2021 that "[n]one of the 25 large insurers that responded to a Bloomberg News survey judged the $56,000-a-year drug "medically necessary. . . . Insurers cited uncertainty about benefits and side effects for their denials." By late December 2021, Biogen announced that it would cut the annual price of Aduhelm in half, down to $28,200, effectively acknowledging that its initial representations about the treatment's pricing being the result of constructive engagement with payers and other stakeholders were untrue.

22. Fifth, Defendants made false and misleading statements about the Veterans Administration's willingness and capacity to cover and administer the treatment of Aduhelm for eligible beneficiaries. A number of Biogen's former employees have confirmed that VA sites first coded by Biogen as "ready" to administer Aduhelm were, in fact, either known to be lacking the requisite medical infrastructure to provide the treatment or had not been evaluated at all because of the VA's unwillingness to provide access to such sites during the Covid-19 pandemic. At least one former employee of Biogen has stated that a leading VA advisor, Dr. Andrew Budson, conveyed to Biogen's medical science liaison, Johannah Venturini, prior to the start of the Class Period, that he did not support the VA covering Aduhelm.

23. Finally, Healthcare providers were aware of the controversy surrounding FDA approval of Aduhelm and wanted to see peer-reviewed data to confirm the drug's benefits. The controversial nature of the approval led many healthcare providers to take a skeptical and dim view of the drug and wait to see the peer reviewed data, which led to limited sales of Aduhelm.

24. As the truth about Aduhelm emerged, Biogen's share price declined. During and by the end of the Class Period, Defendants acknowledged that the treatment was not actually available at 900 sites, bottlenecks relating to confirming the presence of amyloid beta had substantially curtailed sales, Biogen cut the price of the treatment in half in response to objections raised by the same stakeholders it had claimed to have engaged with on the issue of price, the VA had refused to include Aduhelm in its formulary, and the FDA's approval of Aduhelm was the subject of multiple governmental investigations.

25. On January 11, 2022, after the close of stock trading, CMS released its draft opinion, limiting Medicare reimbursement for Aduhelm to patients enrolled in ongoing clinical trials – effectively contradicting Biogen's claim that Medicare coverage was automatic following

FDA approval. On January 12, 2022, Biogen's stock price fell by $16.18 per share to close at $225 per share.

26. After the Class Period, Biogen replaced Vounatsos as CEO, terminated its entire Aduhelm sales force, and effectively abandoned Aduhelm as a commercial drug.

II. JURISDICTION AND VENUE

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

28. 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.

29. 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.

30. 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

31. 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.

32. 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."

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

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

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

36. Collectively, Defendant Vounatsos, Sandrock, and Alaimo, are referred throughout this complaint as the "Individual Defendants."

37. 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

38. Biogen is a global biopharmaceutical company focused on the research, development, production, and sale of pharmaceutical treatments for serious neurological and neurodegenerative diseases. As noted above, Biogen's work developing Aduhelm dates to at least 2007.

39. 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 the prevention and treatment of neurological decline from Alzheimer's disease and dementia. However, a significant percentage of the population of individuals diagnosed with Alzheimer's disease will test negative for the presence of amyloid beta in the brain.

40. During the Class Period, confirming the presence of amyloid beta in a patient, required either a PET scan, costing typically cost around $5,000 and ordinarily not covered by insurance, or an analysis of sample cerebrospinal fluid ("CSF") drawn from a lumbar puncture, also called a spinal tap, usually costing between $800 to $1,000. Confirmation of amyloid beta was a prerequisite for an individuals' inclusion in Aduhelm's clinical trials, discussed in greater detail below.

41. Administering Aduhelm and monitoring patients receiving the treatment is both time consuming and infrastructure intensive because Aduhelm is administered as an intravenous infusion over approximately one hour every four weeks, and patients being treated with Aduhelm are required to get regular MRIs to monitor for potentially dangerous side effects, known as ARIA, including brain swelling and hemorrhages.

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

42. 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.

43. 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.

44. 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.

45. 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 Tecifidera, 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%.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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, Tecifdera 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 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.

51. 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.

B. The Development, Failure, and Resurrection of Aduhelm

52. Biogen first licensed Aduhelm from Neuroimmue 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.

53. 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.

54. 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.

55. After a few months of review, in March of 2019, Biogen, advised by its independent outside experts, concluded neither ENGAGE nor EMGERGE showed sufficient clinical benefit to submit Aduhelm for FDA approval. The outside advisors recommended, and Biogen decided, that submission of the treatment would be futile, and the treatment be abandoned.

56. 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.

57. 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.

58. 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 Aduhlem 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.

59. 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."

60. 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. And we have now established a cross-functional team dedicated to site readiness, which is currently operational."

61. This cross functional team would feature prominently in Biogen's communication to shareholders over the next year.

62. As early as April 2020, months before the Company submitted Aduhelm for FDA approval, Biogen employees designated "Alzheimer's Account Managers" began the process of evaluating treatment sites for their "readiness" to prescribe and administer Aduhelm in anticipation of FDA approval of the treatment. This effort involved a multi-dimensional evaluation of prospective treatment sites and involved Biogen employees working directly with medical providers in a variety of settings, including infusion sites, hospitals, imaging centers, neurology practices and pain clinics.

63. The work was meant to assist with Biogen's evaluation of demand for Aduhelm, if it was approved, as well as site capacity and scalability for potential patient treatment.

64. Sites evaluations were tracked first in Excel, and later in a CRM system called Javelin, and thereafter a system called Veeva and Qliksense. Javelin reporting was designed to measure what Biogen bench marked as having "Willingness, Capacity, and Scalability" at different treatment sites.

65. These benchmarks were measured on five different metrics: potential patient demand for Aduhelm, the presence of necessary specialists to administer treatment and monitor patients, the ability for the site to confirm amyloid beta in patients, the ability of the site to administer Aduhelm as an infusion, and the ability of the site to use MRIs to monitor patients.

When Biogen would speak about sites being "ready to treat patients" after FDA approval, they were referring to those sites being deemed ready on these five metrics.

66. Progress towards evaluating site readiness across various geographies were reported via Javelin and later Veeva, then up to what Biogen designated as "directors" of different regions. While the underlying tracking contained data for 5 different complex metrics, the reports generated (then rolled up to a national level) by Javelin and shown to supervisors and executives utilized a simple red (not ready) to green (ready) color-coded system. Those sites that were coded as green were deemed to be ready to administer Aduhelm very soon after its approval.

67. 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.

68. 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

69. 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. Our teams have evaluated the availability of specialists, infusion capacity, the ability to confirm the pathology of amyloid beta, MRI capacity and formulary approval processes. We believe there are several hundred sites in the U.S. that are ready to start treating patients should [Aduhelm] be approved.

70. 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.

71. 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.

72. 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:

> And while we speak, Biogen is ready to launch [Aduhelm]. We have deployed a cross-functional team in order to work on site readiness all around the country. And while we speak and as communicated during the Q4 call, we have several hundred sites ready to care for the patients, that potentially will come to the centers to be treated.

73. Vounatsos also described the potential risks to success in commercialization:

> We need to keep in mind that while epidemiology is tremendous, there are also some bottlenecks and constraints that we continue to work on to the limit of what one company, one player can do. But this is where we need partners and support from different players. So the amyloid beta potential confirmation needs to be ready and with a capacity in order to take care of that many patients. And beyond PET imaging, we have also CSF opportunities with Fujirebio filed in the U.S. and approved in Europe. And we know, thankfully that are some blood-based diagnostics that are progressing very well.
>
> So all in all, the team, I'm pleased with the progress that the team has made. We hired people mostly who had experience in those centers. And this helped tremendously. I had the opportunity to spend half a day a couple of weeks ago with the U.S. team. I'm pleased with the progress. **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. [Emphasis added.]

74. Finally, Vounatsos described Biogen's work on determining a price for Aduhelm:

> 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.

75. Vounatsos' statements conveyed to investors that Biogen was ready to commence commercial sales of Aduhelm upon approval by the FDA. He claimed "several hundred sites" were ready to care for patients, that Biogen was "set with price" and that it was ready to begin sales. Investors thus understood that all that was in the way of Aduhelm being prescribed was FDA approval.

76. 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.

77. 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.

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

> 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.

79. Also, on the April 22, 2021, Earnings Call, Vounatsos claimed:

> We know that the availability of specialist and diagnosis capabilities are a bottleneck, so we had to prepare the sites of care and we have worked all around the country in order to identify those today. We anticipate approximately 600 ready-to-treat, but many more on the works.
>
> We are pleased with where we are in terms of those sites and their ability to welcome the patients, to diagnose the patients, to dose the patients, to monitor the patients, including the fine processes such as formula relisting, who is in charge of what. So the team has done a very thorough work, and I am pleased with the progress each time I review the operation in the U.S. and the launch readiness, we are bridging, we are passing some new milestones.

80. 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.

81. Vounatsos conveyed to investors that there were 600 sites ready to treat Aduhelm patients and that the potential bottleneck of specialists and diagnosis capabilities – the requirement to determine if patients had amyloid beta – was addressed as Biogen "prepare[d] the sites of care" suggesting little to no obstacles to treatment. He also conveyed to investors that Biogen was "there" on price, stating that it had a "thorough engagement with different stakeholders" suggesting that pricing would be either well-received or not opposed by these stakeholders. Vounatsos informed investors that his statements were based on his "review [of] the operation in the U.S. and the launch readiness" providing investors with comfort that his statements were based on then-existing facts regarding the launch readiness for Aduhelm.

82. During this call, Vounatsos was asked by Michael Yee, an analyst at Jefferies, to give further detail about the work that had been done to make treatment sites ready. Vounatsos responded "we know that the availability of specialist and diagnosis capabilities are a bottleneck, so we had to prepare the sites of care and we have worked all around the country in order to identify those today. We anticipate approximately 600 ready-to-treat, but many more in the works." As discussed below, former employees knew firsthand, many of the sites Vounatsos was describing as "ready-to-treat" had barely been evaluated. In some cases, as with VA facilities, sites had not been evaluated at all, because of the VA's no contact policy in place during the COVID-19 pandemic. Further, some sites that had been evaluated lacked the necessary and required information to include a new treatment in their formulary, such as an FDA label, coverage information/pricing, and peer reviewed and published articles.

83. In the same conference call, further explaining work that had been done in response to Michael Yee, Vounatsos said: "the team has done very thorough work, and I am pleased with the progress each time I review the operation in the US and the launch readiness, we are bridging,

we are passing some new milestones." If he had reviewed U.S. operations multiple times, Vounatsos would have known that much of the work that coded sites as ready could not have been as thorough as he described as sites would not commit to infusing patients with Aduhelm until after the drug was approved, the label was established, pricing was set, and reimbursement established, making a claim that there were "600 ready-to-treat" materially false.

D. The FDA's Controversial Approval of Aduhelm

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

E. Former Employees of Biogen and the Realities of Aduhelm's Commercial Rollout

85. Eight former employees of Biogen have spoken with Lead Plaintiff's counsel and their investigators to provide first-hand accounts of Biogen's efforts to commercialize Aduhelm. Biogen has discontinued its efforts to sell Aduhelm and terminated its entire Aduhelm work force. While many more former employees wanted to provide information, they signed confidentiality agreements with Biogen pursuant to which they felt constrained from stating what they knew about Biogen's misleading its investors concerning its efforts to commercialize Aduhelm.

86. Former Employee 1 ("FE 1") was an Alzheimer's Account Manager at Biogen from April 2020 until the Aduhelm program was shut down in May 2022. They covered territory in the mid-western part of the country. Their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. Any location that was evaluated was referred to as a "treatment site" by Biogen. These were infusion sites, hospital health systems, imaging centers, private neurology practices, and pain clinics.

87. Before FDA approval, their day-to-day duties involved educating and evaluating treatment sites in preparation for treating patients as quickly as possible after FDA approval. After FDA approval, their responsibilities remained largely the same, though metrics and how they evaluated readiness changed. Some of the work was technical, such as ensuring the site had the proper asset allocation, viable work streams, and trained personnel to evaluate potential patients and then prescribe and administer Aduhelm. Some of the work was educational, such as training providers on who would be appropriate for Aduhelm based on the patient profile and utilization of a Medical Science Liaison. Their job also involved measuring demand for the drug if it was approved and determining at what capacity or scalability the site could treat patients.

88. As part of their work, FE 1 used several different electronic tracking tools. Initially, these were shared Excel documents that tracked and showed progress along various metrics. Eventually, that information was put into a CRM system called Javelin. Later, Biogen stopped using Javelin and began using systems called Veeva and Qliksense. Biogen provided training materials on how to evaluate the readiness of various sites.

89. Javelin reporting was designed to measure what Biogen benchmarked as having "Willingness, Capacity, and Scalability" at different treatment sites. These benchmarks were

measured based on five different categories: potential patient demand for Aduhelm, the presence of necessary specialists to administer treatment and monitor patients, ability for the site to confirm amyloid plaques in patients, ability of the site to administer Aduhelm as an infusion, and ability of the site to use MRIs to monitor patients. When Biogen would speak about sites being "ready to treat patients" after FDA approval, they were referring to those sites being deemed ready on these five metrics.

90. Progress towards deeming site "readiness" was broken down by Account Manager geography with teams, like those of FE 1 and FE 2, working across the country. In Javelin, then Veeva, the progress in the various geographies were reported up to what Biogen designated as "directors" of the different regions. While the underlying tracking contained data for 5 different complex metrics, the reports generated (then rolled up to a national level) by Javelin and shown to supervisors and executives utilized a simple red (not ready) to green (ready) color-coded system. Those sites that were coded as green were deemed to be ready to administer Aduhelm very soon after its approval.

91. Throughout FE 1's time at Biogen, there were serious issues both with evaluating sites and getting them ready for approval, as well as how that data was reported within Biogen. FE 1, as well as other Account Managers, persisted in asking senior level leadership to define site readiness. Most prominently, many potential treatment sites flat-out refused to move forward at all until they could evaluate peer-reviewed data on Aduhelm, which Biogen could not provide even six months after FDA approval. Despite repeated requests to Biogen for data to use when working with treatment sites, Biogen did not have any to provide. This was not a minor issue; many hospitals and clinics will not put a treatment within their formulary – the list of treatments they will prescribe and administer to patients – without being able to look at peer-reviewed data, as well

as having detailed reimbursement or insurance coverage information. Consistently, sites would partially move forward with one aspect of the care pathway and be deemed ready by Biogen's teams despite knowing that before Aduhelm would be entered into the formulary for that site, they would need to be given peer reviewed data. As a result, there were locations deemed "ready" by Biogen at the launch of Aduhelm that would still need to undertake a time-consuming evaluation of data that Biogen did not provide to treatment sites until well after the end of the Class Period.

92. Additionally, data regarding "Site Readiness" of treatment sites was spoken of by senior members of Biogen internally and externally in ways FE 1 knew to be inaccurate. FE 1 was able to see first-hand how the "Readiness" numbers reported were used by Biogen executives in their communications to shareholders and co-workers, and FE 1 and FE 2 would often discuss what they saw as discrepancies between their work, as well as the definition of "Site Readiness," and what was reported publicly.

93. Over the course of their employment at Biogen, FE 1 came to believe that the site readiness data included a range of inaccuracies or outright fabrications. FE 1 does not believe their conclusions or experience was an outlier amongst people doing the same work as us in other parts of the country.

94. FE 1 first became concerned with how Biogen was reporting data in March 2021. In a meeting with a Senior Director of Access and Reimbursement, they reported that, contrary to how sites are being coded as ready, the truth was far more complex, and that they believed very few of the sites Biogen was counting as ready to administer Aduhelm would be able or willing to do so. They told the Senior Director explicitly that there was no way 600 sites were ready nationally.

95. On April 14, 2021, FE 1, FE 2, and their team were instructed by their supervisors at Biogen to code all treatment sites that were administered by the VA as fully ready in Javelin, regardless of their actual status.

96. FE 1 learned that Vounatsos, in his remarks in Biogen's Q1 2021 earnings conference call reported that Biogen "believe[d] that more than 600 of these sites will be ready to treat patients shortly after a potential approval." This came one month after telling the Senior Director that FE 1 and FE 2 believed there was no way 600 sites coded in Javelin as "ready" were actually ready. From what FE 1 saw in their own work, Vounatsos's statement could not possibly be true. Many of the sites coded as "ready" were sites they were told to code that way, regardless of status (such as sites run by the VA). After speaking to coworkers in other regions, FE 1 was shocked that these statements had been made publicly.

97. As FE 1 knew firsthand, many of the sites Vounatsos was describing as "ready-to-treat" had barely been evaluated. In some cases, as with VA facilities, sites had not been evaluated at all, because of the VA's no contact policy in place during the COVID-19 pandemic. Further, some sites that had been evaluated lacked the necessary and required information to include a new treatment in their formulary, such as an FDA label, coverage information/pricing, and peer reviewed and published articles.

98. FE 1 believes that Vounatsos, by his own admission, knew of these problems as Vounatsos said: "the team has done very thorough work, and I am pleased with the progress each time I review the operation in the US and the launch readiness, we are bridging, we are passing some new milestones." If he had reviewed U.S. operations multiple times, Vounatsos would understand that much of the work that coded sites as ready could not have been as thorough as he

described, given the difficulties Biogen faced interfacing with potential sites and the pressures to mark sites as "ready".

99. FE 1 believes that being instructed to blanket code VA sites as ready without underlying justification is one of the more egregious examples of being directed to report false data that then went to shareholders. FE 1 believed that the entire structure of the program financially incentivized employees to code sites as ready via regional and nationally set goals for readied sites. But until the treatment was actually approved, Biogen simply could not provide all of the details that are vital for hospitals to offer a new treatment (such as cost/coverage and peer-reviewed data) and thus it was not truly possible to know the outcome. Just because a site had all the pieces to the care pathway for treatment with Aduhlem did not guarantee they would offer it.

100. On April 28, 2021, FE 1 received a call from Biogen employee relations informing them that Biogen was conducting an internal investigation into the Javelin site ready tool. FE 1 participated in an interview over a virtual platform with Biogen's employee relations team. After this interview FE 1 was never informed about the outcome of the investigation. When FE 1 followed up with Employee Relations, in July 2021, they were told that the concerns about sites being misidentified as being ready were "no big deal," and that the investigation had been closed. They went on to say moving forward they would do a "better job with word choices."

101. On May 13, 2021, Deb Glasser, Biogen's VP in charge of Alzheimer's Franchise sent an email to all employees on the Aduhelm site preparation team regarding the current status of the program, including FE 1. For the first time, she referred to sites that had been coded as "ready" as being "potentially commercially ready," hedged language that was seemingly a concession to the fact that many sites reported as being ready were anything but. This was also very different than how FE 1 had heard Biogen executives discuss readiness of sites in the past.

102. Throughout FE 1's time working for Biogen on Aduhelm, it was a regular subject of discussion among co-workers that Biogen executives were telling the public information that was directly at odds with what they knew to be true. FE 1, and others, raised these issues with Biogen leadership, and to employee relations as part of an individual interview.

103. Former Employee 2 ("FE 2") was also an Alzheimer's Account Manager. FE 2 worked with FE 1 in the mid-western part of the country. Like FE 1, their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. As with FE 1, the treatment sites FE 2 evaluated included infusion sites, hospital health systems, imaging centers, private neurology practices, and pain clinics.

104. Before the FDA's approval of Aduhelm, as with FE 1, FE 2's day-to-day duties involved educating and evaluating treatment sites in preparation for treating patients as quickly as possible after FDA approval. After FDA approval, their responsibilities remained largely the same, though metrics and how they evaluated readiness changed. As with FE 1, some of the work was technical such as ensuring the site had the proper asset allocation, viable work streams, and trained personnel to evaluate potential patients and then prescribe and administer Aduhelm. Some of the work was educational, such as training providers on who would be appropriate for Aduhelm based on the patient profile and utilization of a Medical Science Liaison. Their job also involved measuring demand for the drug if it was approved and determining at what capacity or scalability the site could treat patients.

105. Like FE 1, as part of their work, FE 2 used several different electronic tracking tools, starting with Excel and eventually transitioning to Javelin and later Veeva and Qliksense.

As with FE 1, Biogen provided FE 2 training materials on how to evaluate the readiness of various sites.

106. FE 2 shares FE 1's understanding that Javelin reporting was designed to measure what Biogen bench marked as having "Willingness, Capacity, and Scalability" at different treatment sites. These benchmarks described were measured on five different metrics: potential patient demand for Aduhelm, the presence of necessary specialists to administer treatment and monitor patients, ability for the site to confirm amyloid plaques in patients, ability of the site to administer Aduhelm as an infusion, and ability of the site to use MRIs to monitor patients. When Biogen would speak about sites being "ready to treat patients" after FDA approval, they were referring to those sites being deemed ready on these five metrics.

107. Like FE 1, FE 2 understood that while the underlying tracking contained data for five different complex metrics, the reports generated by Javelin and shown to supervisors and executives utilized a simple red (not ready) to green (ready) color-coded system. Those sites that were coded as green were deemed to be ready to administer Aduhelm very soon after its approval.

108. FE 2 also confronted serious issues both with evaluating sites and getting them ready for approval throughout their time at Biogen, and shared FE 1's concerns about how site readiness data was reported within Biogen. FE 2, as well as other Account Managers, persisted in asking senior level leadership to define site readiness. FE 2 also engaged with many potential treatment sites that flat-out refused to move forward at all until they could evaluate peer-reviewed data on Aduhelm, which Biogen could not provide even six months after FDA approval. Despite repeated requests to Biogen for data to use when working with treatment sites, Biogen did not have any to provide. FE 2 shares FE 1's understanding that the lack of peer-reviewed data was not a minor issue; many hospitals and clinics will not put a treatment within their formulary without

being able to look at peer-reviewed data, as well as having detailed reimbursement or insurance coverage information. Consistently, sites would partially move forward with one aspect of the care pathway and be deemed ready by Biogen's teams despite knowing that before Aduhelm would be entered into the formulary for that site, they would need to be given peer reviewed data. As a result, there were locations deemed "ready" by Biogen at the launch of Aduhelm that would still need to undertake a time-consuming evaluation of data that Biogen did not make available until March 2022.

109. Additionally, data regarding "Site Readiness" of treatment sites was spoken of by senior members of Biogen internally and externally in ways FE 2 personally knew was inaccurate. FE 2 was able to see first-hand how the "Readiness" numbers reported were used by Biogen executives in their communications to shareholders and co-workers, and FE 2 and FE 1 would often discuss what they saw as discrepancies between their work, as well as the definition of "Site Readiness," and what was reported publicly.

110. FE 2 also learned of inaccuracies or outright fabrications of the data regarding site readiness during their employment at Biogen. FE 2 shares FE 1's understanding that others doing the same work in other parts of the country were similarly concerned that some site readiness data was inaccurate or fabricated.

111. FE 2 became concerned with how Biogen was reporting data in March 2021. As noted above, in a meeting between FE 1, FE 2, and a Senior Director of Access and Reimbursement, they reported that, contrary to how sites are being coded as ready, the truth was far more complex, and that they believed very few of the sites Biogen was counting as ready to administer Aduhelm would be able or willing to do so. They told the Senior Director explicitly that there was no way 600 sites were ready nationally.

112. On April 14, 2021, FE 1, FE 2 and their team were instructed by their supervisors in Biogen to code all treatment sites that were administered by the VA as fully ready in Javelin, regardless of their actual status. FE 2 informed their supervisor, via email, that such coding was starkly at odds with the reality of those treatment sites – at least one site FE 2 was instructed to code as ready they had never contacted. Because of COVID, the VA had instituted a no contact policy nationally which prohibited us from interacting at that time. Some VA sites could never be "ready,": one VA site in FE 2's territory, for example, had no neurologist on staff – they referred to a community neurologist. This coding was implemented despite the sites themselves either not being ready or Biogen not having done sufficient evaluation to properly evaluate capacity. Reporting these as ready when they were not distorted the overall picture of the entire country's readiness for Aduhelm's launch.

113. FE 2 learned that Vounatsos in his remarks in Biogen's Q1 2021 earnings conference call reported that Biogen "believe that more than 600 of these sites will be ready to treat patients shortly after a potential approval." This came one month after telling the Senior Director that they knew there was no way 600 sites coded in Javelin as ready were actually ready. From what FE 2 saw in their own work, Vounatsos's statement could not possibly be true. Many of the sites coded as "ready" were sites they were told to code that way, regardless of status (such as the VA sites). Speaking to coworkers in other regions, FE 2 was surprised that these statements had been made publicly.

114. As with FE 1, FE 2 believes that Vounatsos knew of these problems with site readiness coding.

115. FE 2 believes that being instructed to blanket code VA sites as ready without underlying justification is one of the more egregious examples of being directed to report false

data that then went to shareholders. The entire structure of the program financially incentivized employees through regional and nationally set goals for readied sites. But until they had the treatment approved and Biogen could provide the details that are vital for sites to offer a treatment (such as cost/coverage and peer-reviewed data) it was not truly possible to know the outcome. Just because a site had all the pieces to the care pathway for treatment with Aduhelm did not guarantee they would offer it.

116. On April 28, 2021, FE 2, like FE 1, received a call from Biogen employee relations informing them that Biogen was conducting an internal investigation into the Javelin site ready tool. FE 2 also participated in an interview over a virtual platform with Biogen's employee relations team. After this interview FE 2 was never informed about the outcome of the investigation. When FE 2 followed up with Employee Relations, in July 2021, they were told that the concerns about sites being misidentified as being ready were "no big deal," and that the investigation had been closed. They went on to say moving forward they would do a "better job with word choices."

117. On May 13, 2021, FE 2 also received the team-wide email from Deb Glasser, Biogen's VP in charge of Alzheimer's Franchise concerning the current status of the site preparation program. In the email Glasser wrote that "[a]s of May 10, 826 sites are potentially commercially ready . . ." For the first time, she referred to sites that had been coded as "ready" as being "potentially commercially ready," hedged language that was seemingly a concession to the fact that many sites reported as being ready were anything but. This was also very different than how FE 2 had heard readiness of sites referred to in the past.

118. On September 24, 2021, FE 2 received an email informing them that all access to what was called "ready accounts" – the ability to deem a treatment site ready – had been locked

and any changes they wanted to make to the status of sites in the system had to be sent to supervisors for input. This was a dramatic change in procedure, and centralized reporting above the level where interactions were happening with sites. Through discussions with co-workers, FE 2 determined that FE 2 was not being singled out: employees at their level across the Aduhelm team were being treated similarly. Additionally, access to Biogen internal data and metrics being used in determining readiness through the Javelin system was discontinued nationally; the data would transition to the new Veeva platform. FE 2 learned this was also happening to those in their position in other regions. FE 2 believes this reduced access was in response to their concerns and in conversations with coworkers across the country these feelings were being echoed by many.

119. Throughout FE 2's time working for Biogen on Aduhelm, it was a regular subject of discussion among their co-workers that Biogen executives were telling the public information that was directly at odds with what they knew to be true. FE 2, and others, raised these issues with Biogen leadership.

120. Former Employee 3 (FE 3) was an Access and Reimbursement Manager for Biogen from October 2020 to November 2021. Their job responsibilities included evaluating infusion site assessments. As noted above, Aduhelm is a treatment that must be administered via intravenous infusion. FE 3's assigned territory was in Central California and Las Vegas, Nevada. They were one of 130 similar employees across Biogen's U.S. operation. FE 3 was not part of the sales team.

121. FE 3's manager reported to the Director of Access and Reimbursement, Glen Pauly, who in turn reported to Vice President Angie McEvoy. McEvoy reported to Deb Glasser, the head of the Aduhelm Franchise. FE 3's understanding is that Glasser reported directly to senior Biogen leadership and likely Defendant Vounatsos.

122. FE 3 worked directly with neurologists who would diagnose Alzheimer's patients and with imaging and infusion centers that were to confirm the Alzheimer's diagnosis. The imaging centers would perform either a PET scan or lumbar puncture to allow for CSF analysis to determine if a patient had amyloid beta pathology that warranted a prescription for Aduhelm.

123. FE 3 believes that the real "bottleneck" to administering Aduhelm was the imaging centers, where the patients were to receive lumbar punctures for CSF analysis. FE 3 noted there were three ways to confirm whether a patient had amyloid beta: a PET scan which Medicare would not pay for; a lumbar puncture/CSF analysis; or a blood test. Blood tests were not thoroughly tested in the clinical trials and not widely used.

124. FE 3 believes there were serious problems created by Biogen's reliance on lumbar punctures. First there were no incentives for the imaging centers to commit to performing lumbar punctures on potential Aduhelm patients. The imaging centers earned approximately $2,500 to perform a one- hour PET scan but only $189 for an hour-and-a-half lumbar puncture. There was no separate diagnosis code to confirm amyloid beta so the reimbursement rate for the lumbar puncture was quite low. FE 3 said imaging centers resisted increasing their capacity to perform lumbar punctures due to the low reimbursement rate. It simply was more profitable to perform other procedures.

125. FE 3 said it was widely acknowledged within Biogen that the facilities performing the lumbar punctures were a major bottleneck in getting patients diagnosed to receive Aduhelm. FE 3 participated in frequent conference calls beginning in at least early 2021 to address the deficiency in imaging centers willingness and capacity to perform lumbar punctures. These calls included, among others, Nadine Vangelov, director of the western region, and Vice President Angie McEvoy. McEvoy reported to Deb Glasser, head of the Alzheimer's franchise. FE 3 had

direct conversations with McEvoy regarding the bottleneck at the imaging centers and reluctance to increase their capacity to perform lumbar punctures for CSF analysis. FE 3 said that based on discussions with Vangelov and McEvoy the issue of the imaging center bottleneck was well known. FE 3 said that "Nadine was getting pressure from Angie [McEvoy] to figure it out." FE 3 also said that these managers intimated that the information about the bottleneck was conveyed to more senior managers: "on regional and national calls, it was a topic being addressed. There is a process, everyone has to understand what it looks like because they [patients] need to go through before they get to infusion." FE 3 said meetings on the bottleneck at the imaging centers occurred "all the time" in 2021.

126. With regard to the infusion centers, according to FE 3, infusion centers did not want to engage with FE 3 until after Aduhelm was FDA approved. As FE 3 said, "no one wants to talk to you until your drug is approved." The regular feedback was the infusion centers were "not ready to talk numbers until the drug was approved" adding "why am I going to write these plans and spend all these resources" to be ready to treat patients before the drug is even approved for use.

127. FE 3 also said that neurologists were a bottleneck in Biogen's attempts to deliver Aduhelm. According to FE 3, many neurologists were reluctant to prescribe Aduhelm because of the controversy surrounding it. The big question was "how do we measure response." According to FE 3, doctors "pushed back" on Biogen's efforts to prepare the market for the launch of Aduhelm. There was a "huge shadow of doubt" regarding the drug. There were "conflicting data" and "conflicting camps" of scientists and medical providers. This was a "prescriber issue," according to FE 3.

128. According to FE 3, the controversy surrounding the drug, because it was brought back to market after the initial decision to no longer pursue regulatory approval, created doubt in

the minds of many providers. FE 3 said that Aduhelm was "unique" in that it was "high profile" and "controversial" because the FDA "in collaboration with Biogen" was considering approving the drug. As a result, doctors were particularly insistent on reviewing peer-reviewed data supporting the efficacy of the treatment before they would take steps to prescribe it.

129. Former Employee 4 ("FE 4") worked as a Director of Account Liaisons from March of 2020 to April 2021. Their responsibilities involved overseeing Account Liaisons in their work assessing site readiness. This involved meetings with employees of various treatment sites to measure that site's "Willingness, Readiness, and Scalability."

130. FE 4 reported to Jennifer Mallek, who was the Senior Director of Alzheimer's Accounts Liaisons, East Division. Mallek reported to Chris Baumgartner, Vice President/Division General Manager for the Alzheimer's Franchise. Baumgartner reported to Deb Glasser, head of the Alzheimer's franchise and Glasser reported to Alaimo.

131. FE 4's responsibility was to review the clinical, financial, and operational preparedness of the health systems in their territory to handle the volume of patients after Aduhelm was approved. Health systems were designated into two categories – Tier 1 and Tier 2. Large hospitals and treatment centers, like Mass General Brigham and Boston Center for Memory, were Tier 1 and small hospitals were Tier 2.

132. FE 4 stated that the account liaisons' assessment of a sites readiness were based on an "extremely comprehensive" list of approximately 70 questions that were built into the Javelin system that measured a site's readiness/preparedness. The questions addressed each account's operational, financial, and clinical capabilities and challenges. It included questions about whether the site had enough nurses on staff, capacity for infusion chairs and transportation options. Clinical questions included questions about whether the site's staff was adequately trained to administer a

treatment like Aduhelm and whether it was capable for screening for amyloid related imaging abnormality (ARIA), also known as brain swelling, a side effect of Aduhelm.

133. FE 4 said executives within the Alzheimer's division exerted a "ton of pressure" on account liaison managers to turn sites green as quickly as possible. Biogen set a goal to have 1,200 accounts ready by the time the FDA approved Aduhelm in June 2021.

134. FE 4 said that all VA sites were turned green – ready to treat – despite the VA not allowing any access to any of its sites due to the Covid pandemic. In other words, there was no way to properly assess whether a VA site was ready to treat since it was not possible to gain access to or discuss readiness with VA personnel.

135. FE 4 left their employment at Biogen in approximately April 2021 but said there was a great deal of tension among the various teams to gain access and time with infusion centers. FE 4 said a number of infusion centers asked Biogen employees to stop calling them.

136. FE 4 received weekly readiness reports which documented how many sites were deemed ready to treat. Senior managers, including Jennifer Mallek, Chris Baumgartner, and Deb Glasser were copied on these reports. There were monthly "all hands meetings" hosted by Deb Glasser to review site readiness and data from Javelin. Alaimo participated in some of these "all hands" meetings.

137. FE 4 assisted Mallek in preparing for quarterly meetings Mallek had with Alaimo and Vounatsos to review site readiness.

138. In January or February 2021, FE 4 learned that Dr. Brad Dickerson, the head of neurology and a key opinion leader at Mass General Brigham, conveyed to Biogen that he did not believe Aduhelm would be an effective treatment. FE 4 learned that Biogen's medical science

liaison, Johannah Venturini, met with Dr. Dickerson in this time frame and Dr. Dickerson expressed his opinion that "the [Aduhelm] juice isn't worth the squeeze."

139. FE 4 stated that if such a key opinion leader at such an important institution did not support Aduhelm, it was "earth-shattering" news. FE 4 learned that both Sandrock and Deb Glasser met with Dr. Dickerson to try to assuage his concerns but to no avail. Glasser subsequently informed the Alzheimer's team, including FE 4, that they should stay the course, that Biogen was "extremely confident Aduhelm would be approved" by the FDA regardless of negative feedback from key opinion leaders in the medical community.

140. FE 4 also stated that they were surprised that Biogen coded all VA centers as green, ready to treat. In addition to the fact that the VA would not meet with Biogen employees to allow them to assess site readiness, Dr. Andrew Budson, a key Alzheimer's opinion leader affiliated with Boston University and the VA Boston Healthcare System, conveyed to Vanturini that he did not support Aduhelm for the VA's formulary. Venturini told FE 4, among others, what Dr. Budson told him during a conference call in approximately March 2021. FE 4 knew that without the support of a key opinion leader like Dr. Budson, the VA would not include Aduhelm in its formulary.

141. Former Employee 5 ("FE 5") worked as a Senior Territory Business Manager for Alzheimer's Disease from August 2020 to January 2022. They were responsible for "clinical selling" of Aduhelm. This involved working with doctors directly to convince them to prescribe Aduhelm to patients.

142. FE 5 said there were three main reasons why doctors refused to prescribe Aduhelm: the requirement for a lumbar puncture, the cost of the drug, and unimpressive study results.

143. FE 5 said the requirement for a lumbar puncture was the "no go" for doctors. Most doctors refused to send their elderly patients for a lumbar puncture. Plus, FE 5 corroborates FE 3's observations that it was difficult to even find imaging centers that would perform a lumbar puncture because of the insufficient reimbursement rates.

144. FE 5 said that even doctors who were "excited" for the launch of Aduhelm ultimately refused to prescribe once these doctors learned their patients would be required to undergo a lumbar puncture.

145. FE 5 also said that doctors balked at the price for Aduhelm. They said the price of the drug was "way too high." "Doctors were furious" with the price and stated that their patients "would not be able to pay" and it "would bankrupt Medicare."

146. Additionally, FE 5 received tremendous pushback as to the effectiveness of Aduhelm. FE 5 explained that doctors were worried that there was "no proof" that if amyloid beta was effectively removed from a patient's brain that the patient would be better, that it would "stop Alzheimer's." Doctors also expressed concern that there was brain hemorrhaging that was materializing after the plaque was removed from patients' brains, as evidenced in studies of Aduhelm then publicly reported. FE 5 said doctors worried "how am I going to talk to a patient" and convince them that Aduhelm was worth the extremely high price tag and lumbar puncture.

147. FE 5 said that between June 2021 and when they left Biogen in 2022, only one or two patients received Aduhelm in that time period in their densely populated territory.

148. FE 5 concluded that sales calls were "like going into the ring with Mike Tyson every day." Aduhelm was all over the news and doctors would point to the concerning news about the drug. The sales representatives were "just being beaten up." FE 5 said "the minute it became

getting a lumbar puncture and the cost of the drug, everything fell apart" and doctors refused to prescribe the drug.

149. FE 5 stated that one of the reasons for the problems with convincing providers to prescribe Aduhelm is that Biogen did not engage with providers prior to Aduhelm's approval regarding issues like lumbar punctures and cost. FE 5 had worked on other drug rollouts and initial commercialization rollouts and noted a distinct absence of the collaboration between company and providers they were accustomed to. FE 5 claimed this lack of engagement resulted in significant resistance to the need for lumbar punctures for amyloid confirmation and price of the treatment and could have been avoided.

150. FE 5 also claimed that Biogen did not communicate to providers the need for amyloid confirmation via CSF analysis. The need for a lumbar puncture turned many providers who had been supportive and willing to prescribe the treatment before launch into opponents of the treatment after launch. FE 5 stated that as soon as providers learned of the need for a lumbar puncture and the cost of Aduhelm, enthusiasm for the treatment evaporated.

151. Former Employee 6 ("FE 6") worked as a Territory Business Manager in the Boston area from August 2020 until February 2022. FE 6's responsibilities included the "clinical selling" of Aduhelm to providers, who would then prescribe the treatment to patients.

152. FE 6 had access to the tracking systems used by the Alzheimer Account Liaisons. From this, they saw that all major hospitals within the Boston area were coded as green, or "ready-to-treat" in Biogen's internal tracking system. FE 6 knew before launch that this was inaccurate. FE 6 claims that the Tufts Medical Center was coded "ready-to-treat" in Biogen's systems before launch but had clearly communicated with Biogen its unwillingness to prescribe the treatment. FE

6's colleague told FE 6 that key opinion leaders at Tufts communicated to Kyle Terpek, a Biogen medical science liaison, that Tufts would never support Aduhelm.

153. Like FE's 3 and 5, FE 6 stated that a significant opposition to prescribing Aduhelm was the need for a lumbar puncture to confirm amyloid beta. Physicians were reluctant to send their elderly patients for a lumbar puncture and few sites were willing to perform them because of the low reimbursement rates.

154. FE 6 also confirmed that they were not permitted by the VA to call on any VA sites nationwide because of the pandemic. FE 6 is therefore not sure how or why VA sites were considered "ready-to-treat" sites.

155. Former Employee 7 ("FE 7") worked as a Senior Territory Business Manager from August 2020 to March 2022. As with FE 6, FE 7 was responsible for the "clinical selling" of Aduhelm to providers. They reported to Regional Manager Marcy Ross, who in turn reported to Division Manager Kevin Clifton, who report to Vice President Angie McEvoy. McEvoy reported to Deb Glasser.

156. FE 7 confirms what FE 3, 5, and 6 stated regarding the significant resistance amongst providers to the use of lumbar punctures and CSF analysis to confirm amyloid beta in potential patients. FE 7 noted that "PET imaging was preferred by doctors and patients alike, but it was expensive and not widely accessible" because Medicare would not reimburse for it. Further, FE 7 noted that while there was an imaging center in their territory capable of performing PET imaging – though lack of reimbursement prevented it – "a large portion of the continental U.S. does not have access to PET imaging for beta amyloid confirmation due to the manufacturing-distribution capabilities of the market." Even if there was a plausible pathway to reimbursement

for PET imaging the logistics of how imaging was performed would have kept it from being widely used in most of the country.

157. FE 7 also stated they had a VA treatment site in their territory and that VA sites generally were prime targets for Biogen because the VA reimbursed for PET imaging in contrast to patients under Medicare or Medicare Advantage.

158. Finally, FE 7 stated that they were told by other employees that Chris Baumgartner, Angie McEvoy's peer in the Eastern part of the U.S. had pressured his subordinates to code all VA sites ready-to-treat as reported by FE 1 and FE 2.

159. Former Employee 8 ("FE 8") worked as Senior Territory Business Manager for the Alzheimer's Disease business unit from August 2020 to March 2022. FE 8 work was focused on the mid-Atlantic. FE 8 worked directly with potential prescribers of Aduhelm, including neurologists at private medical practices and the outpatient clinics of major hospitals.

160. FE 8 regularly interacted with medical providers who were adamantly opposed to prescribing Aduhelm and believes Biogen's senior leadership "absolutely knew" that the treatment was divisive. FE 8 believes the divisiveness was based on skepticism about the underlying data submitted to the FDA in connection with Aduhelm's approval, and the Advisory Panel's unanimous recommendation against FDA approval of the treatment.

161. FE 8 stated that lumbar punctures, the lack of peer reviewed data concerning Aduhelm's clinical benefit, and reimbursement issues negatively impacted the commercial performance of Aduhelm following approval by the FDA.

162. FE 8 also stated that Biogen account liaisons inaccurately coded hospitals in their region as ready to administer Aduhelm immediately after approval, when, in truth, these hospitals were not ready for a variety of reasons, including the lack of peer-reviewed data confirming

Aduhelm's clinical benefit, the need to perform lumbar punctures, and the capability of infusion centers to administer the treatment.

163. FE 8 stated that there was a tremendous amount of pressure on Account Liaisons to have a certain number of accounts ready to go once the treatment was approved. FE 8 understood from their discussions with Account Liaisons that Chris Baumgartner pressured them to report sites as ready when there was no evidence the sites were prepared to begin using Aduhelm.

164. FE 8 confirmed that Biogen's employees could not get access to any VA sites during the pandemic and that there was no basis for coding such sites as ready.

F. Defendants' False and Misleading Statements

165. On June 7, 2021, the FDA announced it granted Accelerated Approval to Biogen to begin commercial sales of Aduhelm in the United States. Biogen's stock trading was halted on the morning of June 7, pending the FDA's decision. After the decision was announced, Biogen's stock price skyrocketed.

166. Following the FDA's approval of Aduhelm, Defendants' sought to portray the commercial success of the treatment as all but inevitable, and made false and misleading statements concerning five topics: (i) the number of sites ready, willing, and able to administer Aduhelm immediately after approval; (ii) the significance of logistical constraints on diagnosing patients; (iii) the degree to which Medicare's coverage of the treatment was independent from the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm at a premium price-point, or, indeed, at any price-point absent peer-reviewed data supporting a determination of the treatment's clinical effectiveness; and (v) the VA's willingness and capacity to cover and administer Aduhelm for its beneficiaries.

167. Primed by Vounatsos' statements about Aduhelm's commercial readiness, Biogen's stock price skyrocketed on June 7, 2021, increasing by over $100 per share on the prospects of the potential revenue from Aduhelm, after it was announced the FDA approved it. 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.

168. 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, Berstein 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.

169. 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."

1. Defendants Falsely Claimed 900 Sites Were Ready to Implement Treatment After Aduhelm's Approval

170. 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.

171. On June 8, 2021, Biogen held a conference call with investors and analysts regarding the FDA approval of Aduhelm and the Company's plans for the treatment (the "June 8, 2021, Conference Call"). During the call, Defendants made numerous false and misleading statements about all aspects of Aduhelm's commercialization and finances.

172. During the June 8, 2021, Conference Call Vounatsos described the work done by Biogen to evaluate sites for the Administration of Aduhelm following FDA approval:

> **Based on our work to date, we estimate there are over 900 sites ready to implement treatment with ADUHELM shortly after approval.** These sites include clinical trial centers with currently confirmed amyloid beta positive patients as well as other sites with the necessary infrastructure to diagnose and treat patients. [Emphasis added].

173. Vounatsos' statements on June 7 and June 8 regarding the 900 sites ready to treat patients with Aduhelm was false and misleading when made. As confirmed by FE 1 and FE 2, Vounatsos knew or recklessly disregarded that many sites Biogen had marked as "ready" were blanket coded without individual evaluation, a fact presented directly to Biogen's internal investigation of the issue. FE 1, FE 2, FE 4, and FE 8 confirm that many of the sites listed by Biogen as "ready" lacked the facilities, infrastructure and/or personnel necessary for the administration of Aduhelm. Some sites, such as those run by the VA, were included as "ready-to-treat" despite lacking onsite neurologists and despite their outright refusing allow for onsite inspection by Biogen personnel as a result of the COVID-19 pandemic. FE 1 confirms that VA treatment sites were blanket coded as "ready-to-treat" despite the VA's flat refusal to engage with Biogen employees or allow onsite evaluations of potential treatment sites at all. Moreover, less than a month earlier, Deb Glasser characterized 826 sites as "potentially" ready, as opposed to Vounatsos' blanket statement that they were "ready-to-treat." Plus, Vounatsos knew, or recklessly

disregarded, that many sites would require and had still not undertaken a Pharmacy and Therapeutics Committee review, (a "P&T review"), an essential part of many sites processes for prescribing a new treatment, and which could occur until after FDA approval of Aduhelm. Given Vounatsos' prior statements about his "review [of] the operation in the U.S. and the launch readiness" he either knew, or recklessly disregarded that the 900 sites were not ready to commence treating patients with Aduhelm. Vounatsos' statement created the misleading impression that there were 900 treatment sites in the U.S. primed and ready to administer Aduhelm.

174. Defendant Alaimo also misrepresented the number of sites ready to treat patients:

> Now the really great news is that we expect a core group of these sites that they will be ready to move really quickly. **Now we believe, and you heard Michel say, that there are over 900 accounts ready. Let me tell you what ready means. Ready means that they have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy.** Now that ADUHELM has been approved, we have local teams throughout the entire country that will prioritize the 900 accounts to support site activation, while our expectation is that more sites are going to become ready in parallel. And our teams are laser-focused on getting this product to as many appropriate patients as possible. [Emphasis added].

175. The statement above was false and misleading when made for the reasons set forth in ¶ 173 above. Alaimo also participated in some of the "all hands calls" as stated by FE 4 and Deb Glasser reported directly to Alaimo. Further, as stated by FE 6, some healthcare sites, like Tufts Medical Center in Boston, which had expressly stated that they were unwilling to administer Aduhelm, were none-the-less coded green an included in the count of the 900 treatment sites described by Alaimo above. Alaimo's statement created the misleading impression that there were 900 treatment sites in the U.S. primed and ready to administer Aduhelm.

2. Defendants Omitted Material Facts Concerning Logistical Bottlenecks Associated with Confirming Amyloid Beta in Potential Patients

176. During the June 8, 2021, Conference Call Vounatsos described the potential bottlenecks in commercialization:

> **[T]he desire to confirm amyloid beta pathology by physicians could be a major bottleneck. With this in mind, we have established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access CSF diagnostic laboratory testing to aid the diagnosis of Alzheimer's disease.** And we continue to advocate for PET reimbursement from CMS, joining a coalition of health care organization who supports a revised coverage policy. [Emphasis added].

177. The statement above was misleading when made and omitted material facts necessary to make it not misleading.

178. Vounatsos omitted to reveal the real source of the bottleneck when it came to prescribing Aduhelm was the reluctance of physicians to require elderly patients to endure lumbar punctures to draw cerebrospinal fluid, not the subsequent analysis of those samples. As described above and as confirmed by FE 3, FE 5, and FE 7, Biogen was aware that the need to confirm amyloid beta was effectively a universal requirement for the prescription of Aduhelm, that CSF testing following a lumbar puncture was the only cost-effective method of diagnosis for most potential patients and prescribers, and, critically, that physicians were, in general, extremely reluctant to prescribe lumbar punctures for elderly patients. Plus, as confirmed by FE 3 diagnosis centers were reluctant to perform lumbar punctures due to the economic incentives; they would make more money performing other procedures than lumbar punctures and were therefore reluctant to commit to performing them on a volume basis. Vounatsos's statement misleadingly suggests that the bottleneck would be meaningfully addressed by arranging for Labocorp and Mayo Cliniclabs to analyze the spinal fluid, but the real roadblock to Aduhelm prescription was getting the samples in the first place. Vountasos's omissions misled investors as to the source and significance of the bottlenecks to prescription and thus potential sales of Aduhelm.

179. During the June 8, 2021, Conference Call, Alaimo also misrepresented the source of the bottleneck concerning Aduhelm prescriptions:

> The necessity of testing, as Michel has said, has been left to the judgment of the prescribing physicians. And as the label states, ADUHELM is an amyloid beta-directed antibody. Since there hasn't been an approved therapy that is amyloid beta-directed, amyloid confirmation isn't a routine clinical practice of today, and there is currently no reimbursed test for amyloid. Therefore, the majority of patients have not yet been amyloid confirmed.
>
> But Biogen believes access to this testing should be easily available and affordable. **Therefore, we've established a program, as you heard Michel say in his opening remarks, with Mayo Clinic Labs and Labcorp to help physicians and patients access cerebrospinal fluid diagnostic laboratory testing.** Also, as Michel had referred to, we are continuing to work with a coalition of health care and advocacy organizations to support a pathway to PET reimbursement from CMS, and we believe we will need both the CSF test and the PET reimbursement. [Emphasis added.]

180. This statement was materially misleading when made and omits material facts necessary to make it not misleading in the same way as Vounatsos's statement in ¶ 176 above for the same reasons set out in ¶ 178 above. Alaimo's statement, as with Vounatsos's, emphasizes Biogen's efforts to address the logistical barriers to Aduhelm's prescription by assisting with the laboratory analysis of CSF, and mentions advocacy efforts to expand Medicare coverage for PET scans, without acknowledging that physician reticence concerning lumbar punctures for elderly patients, and testing sites reluctance to perform them due to the economic disincentives, was the most significant source of the bottleneck to amyloid beta testing.

3. Defendants Falsely Characterized Medicare Coverage as Automatic Following FDA Approval

181. During the June 8, 2021, Conference Call, Vounatsos misrepresented that Medicare coverage was "automatically presumed" following FDA approval:

> 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].

182. The above statement was false and misleading when made. Medicare coverage is not "automatically presumed" following FDA approval of a drug or treatment. In fact, the statement above glosses over a complex regulatory process which could have potentially limited reimbursements for Aduhelm in a variety of ways, including one that ultimately substantially restricted Medicare's coverage for the treatment.

183. Specifically, for physician-administered (Medicare Part B) drugs, like Aduhelm, the reimbursement for Medicare-eligible patients can come through two primary routes: (1) regional Medicare fee for service contractors (MACs) and (2) Medicare Advantage (MA) plans. Approximately 65% of Medicare patients are covered by regional MACs, with the remaining ~35% covered by MA plans. Under rules in effect as of January 2020, CMS has the regulatory authority to direct MACs and MA to consider what treatments are "reasonable and necessary" in the course of coverage determinations.

184. Alternatively, CMS has the option to initiate a NCD, formalizing the requirements for reimbursement across all MAC and MA plans. Contrary to Vounatsos's claim above, the possibility of an NCD for Aduhelm was neither hypothetical nor remote. NCDs are not uncommon in circumstances where a treatment is approved under the Accelerated Approval process by the FDA, is expensive, or where there is controversy surrounding a treatment's efficacy, side effects, or safety. Aduhelm fit the bill perfectly, but Vounatsos's statement above falsely denied the possibility of CMS limiting reimbursement for the treatment.

185. In the course of the same conference call, Alaimo went further, stating:

> 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.]

186. Alaimo's statement was false and misleading when made. As with Vounatsos's statement above, it similarly misled investors by repeating the claim that "for Medicare fee-for-service, coverage is automatically presumed with FDA approval" again omitting to reveal even the possibility of a NCD being initiated. As set out in greater detail below, CMS's draft and later final NCD with respect to Aduhelm strictly limited reimbursement to individuals enrolled in ongoing clinical studies – effectively eliminating the possibility that the treatment would be a significant commercial success in the near-term.

4. Defendants Misleadingly Suggested that Third-Party Payors Approved Aduhelm's $56,000 Per Patient, Per Year Price Point

187. 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 for such a patient.

188. After the announcement on June 7, 2021, Defendant Vounatsos, in an interview with CNBC's Power Lunch attempted to justify the price:

> **The price is set at $56,000 a year, during the normal year after lengthy engagement obviously this is important with scientific leaders, pharmaco-economists, payers, private and public payers.** These are in line with our pricing principle. This is after two decades of having no innovation. This will allow sustainability of continuing to invest in our rich pipeline that goes beyond Alzheimer's, Parkinson's, ALS, stroke, neuropathic pain and many more. So, we believe this is a fair price. We'll be working very closely with Medicare that is covering 80%, we believe approximately of the epidemiology, in order to secure sustainability of the system. And, and monitor very closely, the dramatization. Moreover, we are committed not to take any price increase during the next four years.
>
> …
>
> **You know Meg, and we're engaging with Medicare and we're engaging with the private payers since quite a long time.** Do you know that today the cost of Alzheimer's

> is 600 billion to the US in terms of direct and indirect cost. So, it is time without having really a treatment that addresses a defined pathophysiology of the disease, it is really time now that we invest some resources to treatment. [Emphasis added.]

189. The statement above was materially misleading when made. Vounatsos's statement suggests that Biogen had advanced communications with Medicare and other public and private payers and that those entities had approved, acquiesced, or at the very least indicated a willingness to pay the $56,000 per patient, per year price for Aduhelm set by Biogen. In fact, based on the statements of FE 1, FE 2, FE 3, FE 5, FE 6, and FE 8, Biogen knew that many providers and public payors had expressly refused to make any commitments with respect to Aduhelm until after the FDA had made an approval determination and peer-reviewed data concerning the treatments clinical effectiveness had been provided.

190. Indeed, on November 18, 2021, Bloomberg News reported on a survey from 25 large private insurers who stated they would not provide coverage for Aduhelm based on its price. According to the news story, "[m]ost have deemed Aduhelm experimental, while some say they're still evaluating it. Insurers cited uncertainty about benefits and side effects for their denials." It was therefore misleading to suggest that payers would not balk at paying the cost and providing coverage when, clearly, a large number of insurers never made any determination to provide coverage and ultimately decided against coverage.

191. During the June 8, 2021, Conference Call, Chirfi Guindo, Biogen's Executive Vice President of Global Product Strategy & Commercialization, responding to a question from Umer Raffat of Evercore ISI Institutional Equities, represented that Biogen had a solid foundation for its $56,000 per year price tag:

> [**w]e'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 priced ADUHELM at roughly 1/3 the level of cancer immunotherapies and roughly 25% below the average level of psoriasis biologics. **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].

192. Guindo's statement reinforces both Vounatsos' and Alaimo's statements that Biogen had consulted with "policy and pay leaders" for "months" when it determined the price for Aduhelm, that Biogen considered it a "really responsible price" buttressing the statements that suggestions that Biogen had vetted the price of Aduhelm with payers and there was no opposition to the pricing. To the contrary, there was strong opposition to the pricing.

193. Additionally, on the June 8, 2021, Conference Call, Vounatsos described Biogen's $56,000 yearly price tag for Aduhelm:

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

194. Vounatsos's statement was false and misleading when made. Vounatsos's statement suggests that Biogen had advanced communications with Medicare and other public and private payers and that those entities had approved, acquiesced, or at the very least indicated a willingness to pay the $56,000 per patient, per year price for Aduhelm set by Biogen. In fact, based on the statements of FE 1, FE 2, FE 3, FE 5, and FE 6, Biogen knew that many providers and public payors had expressly refused to make any commitments with respect to Aduhelm until after

the FDA had made an approval determination and peer reviewed data concerning the treatments clinical effectiveness had been provided discussed the pricing of Aduhelm.

195. Vounatsos's statements about Medicare coverage being "automatically presumed" was false and misleading for the reasons set forth in ¶¶ 182 - 186.

5. Defendants Falsely Characterized the VA's Willingness and Capacity to Cover and Administer Aduhelm

196. During the June 8, 2021, Conference Call, Vounatsos described an impending agreement with the VA relating to Aduhelm, stating:

> We are pursuing value-based contracts with payers such as Cigna to help streamline patient access to treatment. We are working with providers groups such as CVS as well as the National Associate of Free and Charitable Clinics, which have neighborhood-level reach, with the goal of engaging underserved people in their local communities to provide them with education about mild cognitive-impairment and to enable access to cognitive screening. **And we are working to finalize a multiyear agreement with the Veterans Health Administration in order to support access for veterans.** [Emphasis added].

197. This statement was false when made. As discussed more fully in ¶ 140 above, as early as March of 2021, Biogen knew that key opinion leaders within the VA opposed including Aduhelm in the VA's formulary. Specifically, FE 4 reports that a leading VA advisor, Dr. Andrew Budson, conveyed to Biogen's Medical Science Liaison, Johannah Venturini, prior to the start of the Class Period, that he did not support including Aduhelm in the VA's formulary. FE 1, FE 2, FE 7, and FE 8 additionally confirm that VA sites were not open for evaluation during the pandemic, and therefore it was impossible to determine the readiness, willingness, or ability of such sites to administer Aduhelm. In fact, on August 11, 2021, just two months after Vounatsos claimed Biogen was "finalizing" an agreement with the VA, the VA announced it would refuse to provide coverage for Aduhelm in its formulary at all.

198. In the course of the same Conference Call on June 8, 2021, Alaimo stated:

> Now we do believe patients should have access to ADUHELM, which is why innovative contracting is an important part of our launch approach. **We have engaged, as you might have seen in our press release, with a small number of strategic partners, including Cigna and the Veterans Health Administration, on innovative or value-based contracting.** For example, Cigna and Biogen intend to enter into a value-based contract to ensure there is a streamlined path to access treatment for patients consistent with the population in which ADUHELM was studied. **And with the VA, we are finalizing a multiyear agreement in order to support access to ADUHELM for veterans who are historically underserved and racially diverse.** [Emphasis added].

199. Alaimo's statements above were false and misleading when made. As confirmed by FE 1, FE 2, FE 4 and FE 8 in ¶¶ 97, 112, 134, and 164, VA representatives across the country refused to meet and discuss Aduhelm with Biogen, at least one high level VA opinion leader had expressed opposition to including Aduhelm in the VA's formulary, and less than two months after this statement was made the VA formally refused to place Aduhelm into the VA formulary. Indeed, the VA announced, on August 11, 2021, that it would not add Aduhelm to its formulary list citing "a lack of evidence of a robust and meaningful clinical benefit and the known safety signal."

200. Taken together, Defendant's statements shortly after Aduhelm's approval created the false impression that the approval of Aduhelm by the FDA was the last obstacle to the widespread treatment at a premium price-point. Investors were led to believe that the treatment would be available to patients at hundreds of sites across the country, that bottlenecks to prescribing the treatment had been resolved, that Medicare's coverage was "automatic," that there was widespread support for the treatment's $56,000 per patient, per year cost, and that the VA and Biogen would shortly be entering a multi-year agreement to cover the cost of the treatment for eligible veterans. None of which was true.

201. Stock market analysts reacted positively to the approval and Biogen's commercialization plans. Guggenheim, in their note after the June 8, 2021, Conference Call titled "With Aduhelm Approved Broadly for Alzheimer's, BIIB Looks Poised to Make Billions, Investor

Focus Shifting to Launch/Payer Dynamics; PT to $455" noted that: "We are further encouraged by the steps BIIB has taken so far to prepare for the launch, with manufacturing on track and 900 sites ready to implement dosing in the next 2 weeks." Guggenheim repeated Vounatsos and Alaimo's representations that "[f]or Medicare fee for service, coverage is automatically presumed with FDA approval."

202. Oppenheimer, in a note released the same day, similarly noted "BIIB is primarily targeting 900 + clinical sites with the necessary infrastructure to immediately begin treatment" and that "[w]e're optimistic about BIIB's ability to execute. Oppenheimer also noted that the "900-plus clinical sites targeted for launch are key centers of excellence in large urban areas, facilitating an accelerated update by Aduhelm by AD specialists."

203. Biogen had convinced investors and analysts that prescriptions for Aduhelm were poised to take off immediately upon approval, and its stock price rose accordingly. Over the next two days, Biogen's stock would continue to increase, until it reached its all-time high of $414.71 on June 10, 2021.

G. The Market Slowly Learned that Aduhelm Was Not Being Readily Prescribed, That Third-Party Payers, Including Medicare, Would Not Pay For Coverage and The Entire Stock Price Increase From June 7 Was Eliminated

204. The stock market came to learn that Aduhelm would not be the blockbuster drug it was expected to be. Sales of the treatment were hugely disappointing, there was resistance to price and reluctance to prescribe it, and by the time CMS announced that Medicare would only pay for coverage for patients enrolled in a clinical trial, Biogen's stock price lost the entirety of the gains achieved in the days following the FDA's approval of Aduhelm and the Company's false and misleading statements about the treatments impending commercial success.

205. The gradual revelation of the truth was spurred by several factors – most notably ongoing concern about the treatment's effectiveness, price, and questions about the FDA's approval process which led to the reluctance of physicians to prescribe the treatment. Many of the corrective disclosures identified herein are partially corrective and Defendants continued to mislead investors regarding Aduhelm.

206. Following the approval of Aduhelm, three members of the PCNS Advisory Panel resigned. On June 8, 2021, Dr. Joel Perlmutter of Washington University at St. Louis and Dr. David Knopman both resigned from the FDA Advisory Panel in protest over the approval of Aduhelm. They were joined on June 10, 2021, by Dr. Aaron Kessleheim of Harvard and Brigham and Women's Hospital who described the approval of Aduhelm as the "worst approval decision the FDA has made that I can remember." Their vocal withdrawals reflected the deep division within the medical community around the effectiveness of the treatment and kept the controversy surrounding the FDA's approval of the treatment in focus.

207. Objections to the treatments price also developed soon after Biogen's stock had hit its all-time high. On June 12, 2021, the Alzheimer's Association, an advocacy group, released a statement deeming Biogen's pricing of Aduhelm at $56,00 a year as "simply unacceptable."

208. On June 21, 2021, the New York Times ran an article headlined "Many Alzheimer's Experts Say Use of Aduhelm Should Be Sharply Limited." The sub headline read "[e]ven those who supported the F.D.A.'s approval of the controversial new drug said authorizing it for anyone with Alzheimer's disease was much too broad." On this news, Biogen's share price dropped from its closing price of $388.44 on Friday June 18, 2021, to close at $380.91 on June 21, 2021.

209. On June 22, 2021, the FDA released documents reporting on "internal strife" within the agency relating to the approval of Aduhelm. It was reported by Investor's Business Daily, in

an article on June 23, 2021, that "FDA biostatisticians objected to the approval, saying the data didn't support it." Biogen's stock dropped $7.23 on June 22, 2021, closing at $374.40 per share.

210. After the market closed on June 23, 2021, Biogen issued a press release in which it stated, in relevant part, that it stood "ready to work with public and private payers to address pricing in order to achieve both patient access and support budget sustainability." It continued that stood "ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments or out-of-pocket expenses for patients treated with ADUHELM." As reported by Bloomberg Business News "Biogen Expects Slow Alzheimer's Drug Uptake, May Reset Price." According to the June 23, 2021, Bloomberg story, "[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 . . ." Also, after the stock market closed on June 23, 2021, the Boston Globe reported that 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.

211. The following day, on June 24, 2021, Biogen's stock price fell from its closing price on June 23, 2021of $371.90 per share to close at $349.16 per share.

212. On June 25, 2021, after the close of the markets, Congresswoman Carolyn Maloney of the U.S. House of Representatives Committee on Oversight and Reform and Congressman Frank Pallone of the U.S. House of Representatives Committee on Energy and Commerce jointly announced an investigation of Aduhelm's approval by the FDA and voiced concern about both the "steep price" and "the process that led to [Aduhelm's] approval despite questions about the drug's

clinical benefit." On this news, Biogen's stock price dropped an additional $3.64 per share to close at $347.93.

213. Biogen sought to re-assure investors that Medicare would provide coverage for Aduhelm. 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 "reasonably and necessary" which means eligible patients are already starting on the therapy.)**" [Emphasis in original.]

214. On the morning of June 28, 2021, before the stock market opened, 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, down from its closing price of $347.93 on June 27, 2021.

215. Between June 21, 2021, and June 28, 2021, Biogen's stock price fell by $48.17 per share, or 12.5%, as news of issues and concerns with Aduhelm began to leak out.

216. On June 29, 2021, StatNews released an exclusive investigate report into the process by which Biogen actively lobbied the FDA for approval of Aduhelm titled "Inside 'Project Onyx': How Biogen used an FDA back channel to win approval of its polarizing Alzheimer's drug". The article detailed a lobbying campaign of the FDA by Biogen that began shortly after the market's strong negative reaction to Biogen's announcement submitting Aduhelm for approval would be futile. Dubbed by Biogen as "Project Onyx" after the first suggested term "Project Phoenix" was deemed inappropriate by Biogen's legal counsel, the program centered on lobbying Dunn and the FDA to disregard the negative clinical data from Biogen's Phase III trials that led to

Biogen deeming approval of Aduhelm futile. The reporting dubbed Dunn "an inside ally" and noted "the FDA played an extraordinarily proactive role, even drafting a road map on how the company could win approval." According to the report, the "new analysis" Biogen had claimed led to filing for approval of Aduhelm was little more than disregarding the negative results of the ENGAGE study. As the results of the Advisory Panel review of Aduhelm shows, the FDA directed the panel to disregard the failed study in their evaluation. The article also claimed the FDA itself recommended Aduhelm be evaluated for approval on its impact on amyloid beta, rather than clinical impact on neurological decline. This approach, in some cases created by, in other cases validated by the FDA, allowed Biogen to falsely market a failed study and a modest success in reducing amyloid plaques in some patients as "therapy to reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease."

217. On July 8, 2021, the FDA changed the prescribing label for Aduhelm, considerably narrowing its recommended use to only those patients in the early stages of the disease.

218. On July 9, 2021, Janet Woodcock, the Acting Commissioner of the FDA requested the U.S. Department of Health and Human Services Inspector General's Office ("HHS IG") to conduct an investigation of the approval of Aduhelm. In requesting the investigation, Woodcock conceded that there may have been contact between the FDA and Biogen "outside the formal correspondence process." Biogen's stock price fell on July 9, 2021, from its prior closing price of $369.05 to close at $358.16.

219. On July 12, 2021, Congresswoman Carolyn Maloney of the U.S. House of Representatives Committee on Oversight and Reform and Congressman Frank Pallone of the U.S. House of Representatives Committee on Energy and Commerce sent a letter requesting documents and records to Defendant Vounatsos regarding Aduhelm's efficacy data and the process by which

Biogen communicated with the FDA regarding regulatory approval, as part of investigation into Aduhelm. The letter contained numerous allegations of improper communications with regulators, pricing, and questions about Biogen's evaluation of the data used to claim Aduhelm provided a clinical benefit. The letter also cited to the Stat News story of June 29, 2021, and Project Onyx.

220. Also on July 12, 2021, a survey of Blue Cross Blue Shield ("BCBS") plans conducted by Formulary Watch showed that BCBS plans in in North Carolina, Michigan, Western New York, and Kansas all had refused to cover reimbursement for Aduhelm, deeming the treatment "investigational."

221. Also 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 treatments such as Aduhelm.

222. 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 then our previous expectations, which is a boon for [Biogen] as the majority of potential Adu[helm] patients are covered by Medicare."

223. Biogen's stock price fell $9.12 on July 12, 2021, to close at $349.04 per share from its closing price of $358.16 per share on July 9, 2021.

224. On July 15, 2021, the Cleveland Clinic became the first of several medical provider networks to issue a statement saying it would refuse to prescribe Aduhelm. Mt. Sinai hospital announced they would also refuse to prescribe Aduhelm the same day. As reported by Bloomberg News in an article dated July 15, 2021, "Biogen's shares sank to their lowest in more than a month after two major hospitals [Cleveland Clinic and Mount Sinai] and a group of health insurers said they wouldn't administer its controversial Alzheimer's disease medicine." In the article,

Bloomberg noted "a number of Blue Cross Blue Shield providers have said they won't cover the controversial treatment" in addition to the news from Cleveland Clinic and Mt. Sinai. Salim Sayed, an analyst from Mizou was quoted as saying "[t]he point hasn't been fully digested by the Street on what it could mean." Biogen's stock closed down 6.79% to $328.16 on July 15, 2021, and 15% off it's high on June 10, 2021.

225. In an expose published on July 19, 2021, the New York Times reported that "an examination by The Times has found that the process leading to approval took several unusual turns, including a decision for the F.D.A. to work far more closely with Biogen than is typical in a regulatory review." The Times reported there was a "close working relationship [between] the F.D.A. and Biogen . . . during the application process. That included meeting several times a week in the summer of 2019 to jointly assess the data and chart a path forward, as well as a joint Biogen-FDA presentation to a committee of independent experts." The New York Times confirmed STAT News report that Sandrock met with Dunn to collaborate on a path forward for Aduhelm. Dunn, according to minutes of a meeting said that "it is imperative that extensive resources be brought to bear on achieving a maximum understanding of the existing data." The meeting minutes continues that "further analyses would best be conducted as part of a bilateral effort involving the agency and sponsor, i.e., through a 'workstream' or 'working group' collaboration." The New York Times quoted a former Biogen employee who said they were "shocked by . . . just how close the interaction was between the teams." The Times reported that former Biogen employees said that FDA officials and Biogen "blurred the expected boundary between a regulator and an official of a company in that regulator's purview." The Times quoted William B. Schultz, former deputy FDA Commissioner and General Counsel for HHS who said "[i]t is not appropriate for F.D.A. officials to collaborate on publications and presentations with employees of companies with applications

pending before those very officials. It undermines the essential arm's-length relationship between the regulator and the regulated industry and destroys the F.D.A.'s credibility as the government agency entrusted with the critical responsibility of deciding the safety and efficacy of drugs." According to the Times, only after the FDA's Medical Policy and Program Review Council found Aduhelm should not be approved was the idea of Accelerated Approval discussed as an alternative means to achieving approval.

226. The unusual, unorthodox and controversial relationship between the FDA and Biogen concerning the approval of Aduhelm undermined the medical communities trust in the drug and, as noted by FEs 3 and 5, was one significant reason why there was resistance among the medical community to prescribing the treatment and underscored the need to independently analyze peer-reviewed data before prescribing the drug.

227. 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 mixed partial corrective disclosures with continuation of misleading statements from the June 8, 2021, Conference Call.

228. On the call, Defendant Vounatsos stated:

> **Of the 900 sites approximately which we expected to be ready shortly after approval, we estimate that approximately 325 or 35% have completed a P&T review with a positive outcome or indicated that they won't require a P&T review**. We have also seen some sites leverage external infusion centers in the face internal resistance or are waiting clarity on their facilities internal process. We continue to believe that consistent with our clinical trials, more specialists will require confirmation of amyloid beta pathology, either via PET or CSF, which is also taking time to schedule and coordinate. [Emphasis added].

229. This statement by Vounatsos serves as the first partial admission by Biogen that their previous description of sites as "ready-to-treat" in pre-class period statements and the June 8,

2021, Conference Call, were misleading and not reflective of the actual status of these treatment sites. Many sites were merely "expected to be ready" shortly after approval. In addition, Vounatsos's description of a "P&T review process" is in fact an acknowledgement that despite having claimed these sites were "ready-to-treat" patients, serious evaluation of Aduhelm was still occurring at many sites, so that, as of June 8, 2021, they were not "ready to treat." As noted above P&T is shorthand for "pharmacy and therapeutics committee reviews," the typical internal processes that hospital systems use to determine if and how they will manage prescribing and administrating a drug, therapy, or treatment.

230. Additionally, Vounatsos claiming that "we believe more specialists will require confirmation for amyloid beta pathology, either via PET or CSF, which is also taking time to schedule and coordinate" mislead investors about the reality Biogen was seeing on the ground. First, providers were not using PET scans to confirm the presence of amyloid beta, because there was no reimbursement for the use of PET scans which were quite costly. The only pathway to confirmation was CSF analysis via lumbar puncture. As confirmed by FEs 3, 5, and 6, the need for a lumbar puncture served as either a bottleneck to treatment due to issues regarding capacity of testing facilities or lack of reimbursement, or a firm barrier to having a patient screened due to the risks of lumbar punctures for elderly patients. A reasonable investor reading Vounatsos's statements in context would still both see the need for amyloid confirmation as a choice by providers – which was not the case, all providers who were willing to prescribe Aduhelm required it – or a surmountable obstacle, when, in fact, the need for a lumbar puncture substantially reduced the overall total market because it was not a logistical or medical possibility for many potential patients.

231. Vounatsos then turned to Aduhelm's price:

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

232. This statement both serves as a partial corrective disclosure to Vounatsos's earlier misstatements, and also continues to mislead investors. First, Vounatsos here partially concedes the reality that, contrary to statements made in ¶¶ 181 - 186 above, reimbursement for Aduhelm was not "automatically presumed" for Medicare following FDA approval and that Medicare had the ability to limit coverage. Both Vounatsos and Alaimo emphasized repeatedly in the June 8, 2021, Conference Call that most of Aduhelm's potential patients were covered by Medicare and that Medicare coverage was "presumed" or "automatically presumed" with FDA approval. See ¶¶ 181 - 186.

233. Vounatsos further misled investors where he claimed Biogen "expect[s] that regional Medicare Administrative Contractors and Medicare Advantage plans will provide coverage for Aduhelm while the NCD analysis was underway" despite employees on the ground interacting with payers and providers experiencing strong pushback and skepticism from networks. As confirmed by FE 5, many providers refused to prescribe Aduhelm during the NCD process because the cost of Aduhelm was so high, they did not want to prescribe a treatment that would not be paid for.

234. Alaimo, in response to a question from Michael Yee of Jeffries on the progress of treating patients a month after approval, stated:

> You might have seen recently published several AD specialists recently said, building this infrastructure for the appropriate use of ADUHELM will require time, resources, and some creative planning. In fact, I recently just visited several sites, and what I saw, is consistent with what we're seeing across the entire country. Sites are currently, right now, developing their protocols. They are reengaging with their patients. They are considering or scheduling amyloid-beta confirmation. They also are ordering baseline MRIs. Then, they are discussing these results of the tests and making the treatment decision with their patients. This has clearly taken quite a bit of time. On our last call with you, we shared a program that we created with Labcorp and Mayo Clinic Labs to help physicians and patients access CSF diagnostic laboratory testing. **We are also seeing a very strong interest in this program**. In fact, we've already seen the first orders come in for both of our lab partners. Sites are also trying to gain clarity, as you said, on the reimbursement pathway. The decision by CMS to open an NCD analysis will help provide additional clarity to sites and healthcare. [Emphasis added.]

235. This statement serves as a partial corrective disclosure, but also continues to create a misleading impression of progress and challenges in the minds of reasonable investors. In discussing treatment sites, Alaimo represented on the June 8, 2021, Conference Call that there were 900 sites "ready-to-treat." Alaimo back-tracks on that statement and now refers to sites as in the process of "developing their protocols," an essential first step in any hope of treating patients. This contradicts how Alaimo described these sites in the June 8, 2021, Conference Call. There, Alaimo described all 900 sites as "ready" which she defined as "ready means that they have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy."

236. Alaimo's descriptions of the challenges still misled investors with regard to the bottleneck which was causing physicians to not prescribe Aduhelm for their patients. In describing the "very strong interest" Biogen saw in the program it created with Labcorp and Mayo Clinic Labs for CSF testing, Alaimo misled investors as there was significant opposition to the need to have an elderly Alzheimer's patient get a lumbar puncture to determine if they were candidates to receive Aduhelm. As confirmed by FEs 3, 4, 5 and 8, the need for amyloid beta testing via CSF

and the resultant need for lumbar punctures was a significant bottleneck and barrier to patient uptake. Alaimo's statement misleads investors and omits to reveal material facts.

237. Alaimo continued, describing the status of reimbursement for Aduhelm:

> Now, while this analysis is underway, coverage decisions will be made by Regional Medicare Administrative Contractors, as you know is 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.
>
> We can also confirm that some Medicare Advantage plans have already approved prior authorizations for ADUHELM. For the MACs, due to the miscellaneous coding, it does take them a little bit of time to process the claims, but we are also aware that MACs have received claims already. So during the NCD analysis, we are actively working with sites to support patient access and reimbursement. Keep in mind, and as I witnessed across the various sites that I visited, each site will operationalize at different rates, which is why patient infusions will build gradually over the year as we've referenced. Though this process will take time, it was absolutely humbling to see how much effort and passion these physicians are putting into building the infrastructure to treat their patients and I'm really proud of how hard our teams are working to support these sites as they break new ground.

238. This statement was misleading as Medicare Advantage plans are run by private insurance companies, and private insurers were balking at Aduhelm's price and denying coverage.

239. Finally, Alaimo, in response to a question from Phil Nadeau of Cowen and Company stated:

> Since PDUFA, we have continued to hear a high level of interest in our ABC program, which I talked about prior, which is the CSF testing, which you heard me talk about in my first answer. Now, the reason why there is a high interest is primarily due to three reasons. First, we're hearing a consistent message from the AD experts and the clinicians, that they will align their patient selection to the patient population studied in our clinical trials.
>
> So 100% of patients in our clinical development program were confirmed for amyloid plaques. However, just so you also know, no one's really come out with the policy yet, so I can't actually tell you that there's been a mandate on amyloid-beta confirmation, but we would expect that, potentially, those will be on the policies. Second, there's currently no reimbursed test to confirm the presence of amyloid, in this program that we offer as a solution to provide access to patients who would otherwise lack the ability to pay for this lab test, let alone the cost of a PET scan.

> And as you know, for PET scanning third, there are still several areas of the country, in particular the Mountain West, Hawaii, and Alaska, where access to amyloid PET is not available due to the distribution of radio pharmacies and limited half-life of the radioligand. But I also said in our prior call that we do need both PET and CSF and we have seen these orders come in for both of our lab partners, and so we're still working diligently with a coalition to see if we can get PET reimbursement through CMS.

240. This statement was materially misleading. Alaimo omitted to reveal that opposition to a lumbar puncture, to obtain a sample of spinal fluid, was a major bottleneck in physicians determining whether their patients had amyloid beta to warrant treatment with Aduhelm.

241. Alaimo's statement that "there's currently no reimbursed test to confirm the presence of amyloid, in this program that we offer as a solution to provide access to patients who would otherwise lack the ability to pay for this lab test, let alone the cost of a PET scan" is materially misleading. Again, the bottleneck to Aduhelm prescriptions, among other things, was the strong opposition to sending elderly dementia patients for lumbar punctures and not the lack of reimbursement for the spinal tap and the solution provided – having two labs that could analyze the CSF – was not the solution to the problem. Plus, testing centers performed few lumbar punctures because they were not well paid for them, creating a hard cap on the procedure being performed, and providers being unwilling to subject elderly patients to a painful and invasive testing procedure. FEs 3, 5, 6 and 7, confirm that few facilities performed a large number of lumbar punctures, the reimbursement structure made it so there was no desire to expand capacity, and few providers wished to subject their patients to the procedure. Biogen's program to cover the cost of analyzing the CSF resulting from lumbar punctures did nothing to alleviate that.

242. The realities of this bottleneck were omitted from Biogen's statements regarding the commercial rollout of Aduhelm.

243. Also on July 22, 2021, prior to the earnings call discussed above, Sandrock posted a letter on Biogen's website defending the FDA approval of Aduhelm. In an unusual letter,

Sandrock wrote that the approval "came after an extensive development, testing and review process." He continued that "ADUHELM'S approval has been the subject of extensive misinformation and understanding. It is normal for scientists and clinicians to discuss data from experiments and clinical trials, to debate, and to disagree, on the interpretation of data. . . . It is important to recognize that collaboration between industry and regulatory agencies is common appropriate and beneficial. . . . Recently, however, there has been a turn outside the boundaries of legitimate scientific deliberation. . . . Separately, we have seen statements that all of ADUHELM'S results are 'post hoc' – in other words, that a filter was applied after the fact to interpret data in a certain way. That is also factually incorrect."

244. Sandrock's statement that Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary was materially false and misleading. Indeed, Acting FDA Commissioner Woodcock, in asking for an investigation by HHS IG conceded there have been contact between the FDA and Biogen "outside the formal correspondence process." Both STAT News and the New York Times reported on an unusually cozy relationship between Biogen executives and FDA regulators, including previously undisclosed meetings to discuss a pathway for approval.

245. Stock market analysts reacted positively to Biogen's representations regarding Aduhelm. BTIG's Thomas Shrader wrote in a research report on July 22, 2021, that "Biogen provided additional color on [Aduhelm] specifically detailing 'misinformation' in the media – a stance we found refreshing. The company reported strong interest from both existing and newly referred AD [Aduhelm] patients for the drug . . .." Morningstar's July 23, 2021, analyst report contained the headline "Maintaining Our $391 FVE for Biogen; Aduhelm a Likely Blockbuster Despite Controversy."

246. On July 27, 2021, Axios reported that Biogen had withdrawn the peer reviewed data from submission to the Journal of the American Medical Association after the journal requested significant edits to the paper. As confirmed by FE1, peer reviewed data was a key requirement to many sites moving forward with Aduhelm.

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

248. On August 11, 2021, the VA announced that it would not add Aduhelm to its formulary list citing "a lack of evidence of a robust and meaningful clinical benefit and the known safety signal." While it is possible for veterans who received VA health care to receive treatments not on the formulary list, the process is detailed and individualized. This decision functionally closed off most veterans as potential patients for Aduhelm. As detailed in ¶¶ 196 and 198 Biogen had claimed it was "finalizing" an agreement with the VA as recently as June 8, 2021. The VA's rejection of Aduhelm served as a partial corrective disclosure relating to Defendants earlier false and misleading statements.

249. 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. In discussing sales of Aduhelm, Vounatsos said:

> Although we are facing some near-term challenges and everybody can see that, we continue to see a very high level of physician and patient interest and continue to believe the mid-to long-term opportunity remains significant. In addition to the launch, in the U.S. Aduhelm is now filed in many geographies, and we are pleased to report the recent regulatory approval in the UAE . . . We all know that in the past, some drugs directed to the same hypothesis and the same target did not show benefit. But we all know that these prior drugs did not lower the amyloid plaque, and this is the key difference. And maybe one of the reason of the polemic we hear. However, nowadays there is clearly too much confusion, misinformation and controversy surrounding our data and the approval process. I can tell you, Biogen stands behind our clinical data for the 8 studies with more than 3,000 patients that supported the accelerated approval, and we stand behind the integrity of the

> review process. . . Although our launch is slower than we initially anticipated for all the reasons you know, we are encouraged.

250. Bloomberg Business News reported on September 9, 2021, that Biogen lost "$7 Billion in Value on Slow Alzheimer's Drug Rollout." According to the news story, the "stock fell for a seventh day on Thursday, solidifying roughly $7 billion loss after management said the introduction of Aduhelm was facing several challenges. . . . 'The launch is slower than we initially anticipated' [Vounatsos] told investors Thursday at the Morgan Stanley Global Health Care Conference." According to the article, Company executives admitted "only about 50 sites have been infusing the medication since June, well below the company's prior target of 900 centers."

251. At the Morgan Stanley Conference, Alaimo stated that "as of this week, we are now aware of approximately 50 sites that are infusing Aduhelm."

252. In discussing continual challenges in commercialization, Alaimo continued:

> In addition, some sites are waiting for our published manuscript before they conduct their P&T reviews, which brings me to the second challenge. During our last earnings call, we shared that sites are in the process of P&T committees. And since that call, we have seen more progress with these formulary decisions. However, after this decision, we are seeing sites experience several operational issues that they need to work through before they can infuse their first patient. And though we did anticipate it would take time, operationalization, the patient journey care pathway is taking longer than we expected.

253. This partially corrects the representations made on June 8, 2021 that there were 900 sites "ready to treat" patients with Aduhelm. Alaimo notes for the first time than many providers are refusing to move forward with P&T reviews at all without Biogen's data from their clinical trials being published after peer review. As stated by FEs 1 and 2, providers had been telling Biogen peer reviewed data was a requirement for them to prescribe, screen, and treat patients for months prior to FDA approval of the drug.

254. However, Alaimo's statement above also continued to mislead as to where the bottleneck in treating patients occurred. Alaimo described much of the hesitation on the part of

doctors as the nuts and bolts of treating patients, from writing protocols, to how to do amyloid confirmation. As confirmed by FEs 3, 5, 6, 7, and 8, however, the main problem with provider willingness to prescribe Aduhelm remained the need for a lumbar puncture to confirm amyloid beta as detailed in ¶¶ 122-125, 142-143, 148-149, 153, 156 and 161 and the significant costs associated with Aduhelm. Alaimo described this as providers "learning how to buy and bill a product" but continues her repeated failure to fully disclose the concrete logistical barriers surrounding the need for lumbar punctures.

255. In response to a question regarding reimbursement for diagnostic tests for Aduhelm by Matthew Kelsey Harrison of Morgan Stanley, Vounatsos stated:

> This is a very important bottleneck that we had identified before and now that has impacted -- impacting the patient journey even more than what we anticipated. And we have partnership with Labcorp, and we have partnership with the Mayo Clinic, and we see the number of LPs increasing. But certainly, if we could get that reimbursed the way it is for oncology, this will certainly accelerate.

256. This statement was misleading when made. As confirmed by FEs 3, 5, 6, and 7 the barrier to more lumbar punctures was a combination of physical capacity of treatment sites and their willingness to perform lumbar punctures, and providers' unwillingness to subject elderly patients to the procedure. This was compounded by the fact that during all relevant times, CSF analysis via lumbar puncture was the only practical method to confirm amyloid beta. Vounatsos reference to the program with Labcorp and the Mayo Clinic does not address the actual source of the bottleneck – diagnostic centers performed few lumbar punctures, and doctors did not wish to prescribe them.

257. 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 6.8% decline.

258. 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." Sunjea wrote that Biogen management stated that the "confusion and misinformation surrounding the Phase III clinical data package for Aduhelm . . . caused hesitancy among some physicians to prescribe the drug; many are waiting until the clinical data has been published in a peer-reviewed journal. BIIB [Biogen] has several manuscripts in progress and plans to have their medical access teams working to educate neurologists on the data once published. The company noted that many infusion sites are waiting for the published manuscript before conducting their P&T review to determine of Aduhelm will be on formulary."

259. This is precisely the information reported by each of the FE's both prior to and right after the FDA approved Aduhelm and was either known, or recklessly disregarded, by Defendants.

260. On November 15, 2021, after the close of trading, Biogen announced the resignation of Sandrock. Bloomberg Business News Reported, on November 16, 2021 that Sandrock played a "key role in the approval of Aduhelm," according to Baird analyst Brian Korney. Bloomberg reported that Korney wrote that Sanrock's departure was "a terrible headline for" Biogen and the "abrupt departure" in the midst of an OIG investigation was not "entirely benign as Sandrock has been the most public voice at the company defending the drug's data and approval process." Bloomberg also reported that "William Blair analyst Myles Minter writes that there will be investor concerns related to the timing of Sandrock's departure given it is so early into the 'troublesome' Aduhelm launch and amid the OIG investigation." Biogen's stock price fell by $9.71 on November 16, 2021, to close at $261.55 per share.

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

262. On November 22, 2021, safety data published in JAMA Neurology showed that 41% of patients taking Aduhelm experienced either bleeding or swelling in the brain. According to Bloomberg Business News, the study published in "JAMA Neurology is one of the first formal publications of data from the company's two final-stage trials of Aduhelm. . . . About 19% of patients who received the dose had brain bleeding that showed up on imaging, which sometimes overlapped with swelling, the study found. A total of 41% of patients had either brain swelling, bleeding or both. Of those cases, 14 were judged to be serious, including some people who were hospitalized." The safety data was published during the day on November 22, 2021. Biogen's stock price opened at $257.97 on November 22, 2021, and closed at $252.21 that day.

263. The next several days saw additional media coverage of the JAMA Neurology study. On November 26, 2021, Bloomberg Business news reported that Biogen's stock price had given up all its gains from its initial announcement of FDA approval for Aduhelm.

264. On November 29, 20212, a daily briefing posted on Advisory Board connected the study about brain swelling and bleeding in Aduhelm patients, the investigation of HHS's Inspector General, and earlier news of the death of a 75-year-old woman who had been participating in a Aduhelm clinical trial. On the same day, Fierce Biotech published an interview with Biogen's Chief Medical Officer, highlighting the controversy surrounding the treatment's approval and the unwillingness of some medical clinics to offer Aduhelm. Biogen's stock price which opened at $245.36 on November 29, 2021, closed at $236.11 per share that day.

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[2] Thanksgiving was celebrated on November 25, 2021. As a result, markets were not open for trading November 25 or 26, and opened again on November 29, 2021.

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

266. In a December 20, 2021, research report headlined "Aduhelm Price Reduction Is A Day Late And A Dollar Short" CGS CIMB analysts wrote that "Biogen indicated it believes with insurance coverage and access to diagnostics and specialized centers, approximately 50,000 patients may initiate Aduhelm in 2022. However, it also highlighted plans to cut costs by ~$500M next year (more details expected in 1Q22). Seems to us that if management was confident that the price reduction would get the Aduhelm launch back on track, then it wouldn't be downsizing its sales force."

267. Also on December 20, 2021, the European Union's Committee for the Medicinal Products for Human Use (the "CHMP") officially rejected Aduhelm for approval in the European union.

268. On December 22, 2021, Biogen announced Japan was also unlikely to approve Aduhelm. With the rejection of both the EU and Japanese drug regulators, Biogen would be almost completely reliant on sales of Aduhelm in the United States. With many providers refusing to prescribe the treatment, some insurance carriers refusing to provide reimbursement for it, Aduhelm's commercial prospects were, by this point in time, entirely dependent the NCD by CMS.

269. On January 11, 2021, 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.

270. 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.

271. 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.

272. 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.

273. On May 3, 2022, Biogen announced that Defendant 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

274. 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 January 11, 2022, 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.

275. 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, 2022, 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.

276. 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.

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

278. 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.

279. 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

280. 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.

281. 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.

282. 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.

283. 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.

284. 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

285. 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) the number of sites ready, willing and able to administer Aduhelm in the near-term; (ii) the significance of logistical constraints on diagnosing potential patients; (iii) the degree to which Medicare's coverage of the treatment was independent from the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm at a premium price-point, or, indeed, at any price-point absent peer-reviewed data supporting a determination of the treatment's clinical effectiveness; and (v) the Veteran's Administration's willingness and capacity to cover and administer Aduhelm for its beneficiaries.

286. 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) the number of sites ready, willing and able to administer Aduhelm in the near-term; (ii) the significance of logistical constraints on diagnosing potential patients; (iii) the degree to which Medicare's coverage of the treatment was independent from the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm at a premium price-point, or, indeed, at any price-point absent peer-reviewed data supporting a determination of the treatment's clinical effectiveness; and (v) the Veteran's Administration's willingness and capacity to cover and administer Aduhelm for its beneficiaries.

287. 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

288. 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.

289. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶ 170, 172, 174, 176, 179, 181, 185, 188, 191, 193, 196, 198, 213, 228, 231, 234, 237, 239, 243, 249, 252, and 255 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 the sense that Biogen had done the groundwork to ensure that Aduhelm's would be a commercial success following the FDA's approval of the treatment.

290. The statements, articles, and events identified herein at ¶¶ 204-269 in Section G, the "The Market Slowly Learned that Aduhelm Was Not Being Readily Prescribed, That Third-Party Payers, Including Medicare, Would Not Pay For Coverage and The Entire Stock Price Increase From June 7 Was Eliminated" served as partial corrective disclosures. As investors digested the partial corrective disclosures, the market began to learn that there were a fraction of

sites available that were "ready to treat" patients, that there was significant pushback on pricing and that Medicare would not "automatically" cover the cost of Aduhelm, that sales of the drug were much slower than what investors were initially led to believe such that the entire stock price increase on the day it was announced the FDA approved Aduhelm on June 7, 2021 was eliminated by the end of the Class Period.

291. On June 21, 2021, the New York Times ran an article headlined "Many Alzheimer's Experts Say Use of Aduhelm Should Be Sharply Limited." The sub headline read "[e]ven those who supported the F.D.A.'s approval of the controversial new drug said authorizing it for anyone with Alzheimer's disease was much too broad." On this news, Biogen's share price dropped from its closing price of $388.44 on June 18, 2021, to close at $380.91 on June 21, 2021. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

292. Investor's Business Daily, in an article on June 23, 2021, reported that "FDA biostatisticians objected to the approval, saying the data didn't support it." After the market closed on June 23, 2021, Biogen issued a press release in which it stated, in relevant part, that it stood "ready to work with public and private payers to address pricing in order to achieve both patient access and support budget sustainability." It continued that stood "ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments or out-of-pocket expenses for patients treated with ADUHELM." As reported by Bloomberg Business News "Biogen Expects Slow Alzheimer's Drug Uptake, May Reset Price." According to the June 23, 2021, Bloomberg story, "[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 . . .” Also, after the stock market closed on June 23, 2021, the Boston Globe reported that 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.

293. 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 caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen’s stock price was partially removed.

294. On June 25, 2021, after the close of the markets, Congresswoman Carolyn Maloney of the U.S. House of Representatives Committee on Oversight and Reform and Congressman Frank Pallone of the U.S. House of Representatives Committee on Energy and Commerce jointly announced an investigation of Aduhelm’s approval by the FDA and voiced concern about both the “steep price” and “the process that led to [Aduhelm’s] approval despite questions about the drug’s clinical benefit.”

295. 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.

296. 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.

297. The news of the investigation opened by HHS IG at the request of the Acting Head of the FDA on July 9, 2021, pushed Biogen's stock down 2.95% to $358.16 on July 9, 2021. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

298. On July 12, 2021, the combination of the announcement of a Congressional investigation, another major private payor refusing to cover the cost Aduhelm, and the CMS's launch of a NCD, pushed Biogen's stock down 2.55% to $349.04 per share. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

299. On July 15, 2021, the news that the Cleveland Clinic and Mt. Sinai hospital would refuse to prescribe Aduhelm pushed Biogen's stock down 6.79% to $328.16. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

300. The statements by Vounatsos and Alaimo at the Morgan Stanley Healthcare Conference on September 9, 2021, that Aduhelm sales were "slower than anticipated" and that there were only 50 sites actually administering Aduhelm caused Biogen's stock price to decline by $21.85 per share, to close at $300.15 representing a loss of approximately $3.2 billion in market capitalization. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

301. On November 22, 2021, safety data published in JAMA Neurology showed that 41% of patients taking Aduhelm experienced either bleeding or swelling in the brain. The safety data was published during the day on November 22, 2021. Biogen's stock price opened at $257.97 on November 22, 2021, and closed at $252.21 that day. This decline caused Lead Plaintiff and

Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

302. On November 26, 2021, Bloomberg Business news reported that Biogen's stock price had given up all its gains from its initial announcement of FDA approval for Aduhelm, By November 29, 2021, Biogen's stock price declined further to close at $236.11 per share. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

303. On November 29, 2021, a daily briefing posted on Advisory Board connected the study about brain swelling and bleeding in Aduhelm patients, the investigation of HHS's Inspector General, and earlier news of the death of a 75-year-old woman who had been participating in a Aduhelm clinical trial. On the same day, Fierce Biotech published an interview with Biogen's Chief Medical Officer, highlighting the controversy surrounding the treatment's approval and the unwillingness of some medical clinics to offer Aduhelm. Biogen's stock price which opened at $245.36 on November 29, 2021, closed at $236.11 per share that day. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

304. Finally, after the end of trading on January 11, 2021, CMS announced that it would only cover Aduhelm for patients in ongoing clinical trials. The next trading day, January 12, 2022, Biogen's share price fell 6.7% to $225. This decline caused Lead Plaintiff and Class members to suffer loss as the artificial inflation in Biogen's stock price was partially removed.

305. 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)

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

307. 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.

308. 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.

309. 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.

310. 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 make, 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) deceived the investing public, including Lead Plaintiff and the Class, regarding, among other things, the number of treatment sites ready willing and able to treat Alzheimer's patients with Aduhelm following the FDA's approval of the drug; the bottlenecks to treatment including opposition to sending patients for lumbar taps; medical provider's desires to review peer-reviewed data before agreeing prescribe Aduhelm; Medicare's "automatic" requirement to pay for treatment of Aduhelm; third-party payers reticence and/or refusal to provide coverage for Aduhelm; the VA's willingness to add Aduhelm to its formulary and the irregular interactions between Biogen and the FDA to obtain approval for Aduhelm;

(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.

311. 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.

312. 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.

313. Lead Plaintiff and the Class has 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.

314. 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)

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

316. 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).

317. By reasons 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.

318. 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.

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

320. 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.

321. 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 BLOCK ON FOLLOWING PAGE]

June 27, 2022

Respectfully submitted,

/s/ Jeffrey C. Block

BLOCK & LEVITON LLP
Jeffrey C. Block (BBO# 600747)
Jacob A. Walker (BBO# 688074)
Bryan J. Jennings (BBO# 705485)
Brendan T. Jarboe (BBO# 691414)
260 Franklin St, Suite 1860
Boston, Massachusetts 02110
(617) 398-5600 phone
(617) 507-6020 fax

Attorneys for Lead Plaintiff Oklahoma Firefighters Pension and Retirement System

Certificate of Service

I, Jeffrey C. Block, hereby certify that a true copy of this document will be sent electronically to the registered participants as identified on the Notice of Electronic Filing at the time it is filed through the CM/ECF system on June 27, 2022.

/s/ Jeffrey C. Block
Jeffrey C. Block