

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO

Civil Action No.

Plaintiff,

v.

JURY TRIAL DEMANDED

BIOGEN INC., CHRISTOPHER A.  
VIEHBACHER, MICHEL VOUNATSOS,  
and MICHAEL R. MCDONNELL,

Defendants.

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CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL  
SECURITIES LAWS

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

substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Biogen securities between February 3, 2022 and February 13, 2024, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Biogen is a global biopharmaceutical company that discovers, develops, and delivers therapies for people living with serious and complex diseases worldwide. The Company operates in various countries throughout the Americas, Europe, and Asia.

3. Biogen’s products include, among others, Leqembi and Aduhelm for the treatment of Alzheimer’s disease (“AD”), as well as various drugs for the treatment of multiple sclerosis (“MS”). Biogen’s sales of its MS-related products have historically accounted for the majority of the Company’s product revenues. However, in recent years, increased competition from generic biosimilars of Biogen’s MS-related products have eroded those products’ revenue growth and led to declining sales. As a result, the Company has increasingly focused on developing new products to bolster its revenues. Accordingly, because AD-related treatments represented a lucrative market for Biogen, the Company’s AD-related products were particularly important to Defendants and investors throughout the Class Period.

4. In 2021, in a major set-back to the Company's development of AD treatments, Biogen was mired in controversy after investigative reports revealed that the Company had engaged in potentially improper communications with representatives of the U.S. Food and Drug Administration ("FDA") to win regulatory approval of Aduhelm for the treatment of AD, despite concerns regarding, *inter alia*, the drug's safety and efficacy. Biogen and the FDA's communications and conduct have been the subject of investigations by the U.S. Federal Trade Commission ("FTC"), SEC, multiple Congressional Committees, and the Office of the Inspector General of U.S. Department of Health and Human Services.

5. Nor were the foregoing investigations the only source of controversy for Biogen. Separately, in 2022, the U.S. Department of Justice ("DOJ") announced that Biogen had agreed to pay \$900 million to settle allegations that it had caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce them to prescribe the Company's MS-related drugs.

6. Following these controversies, Biogen embarked on a campaign to purportedly enhance its transparency, corporate governance, and compliance controls and procedures. Among other things, the Company replaced its Chief Executive Officer ("CEO") in November 2022 and has since released compliance, corporate responsibility, and environmental, social, and governance ("ESG") reports touting the Company's purportedly enhanced compliance and governance practices.

7. Moreover, the controversy surrounding Aduhelm's regulatory approval has, at least in part, led to the drug's failure to gain traction in the lucrative AD-treatment market. Accordingly, Defendants and investors have been particularly focused on the launch of the Company's Leqembi

product, developed in partnership with Eisai Co., Ltd. (“Eisai”), which gained FDA approval as a treatment for AD in 2023. Biogen and Eisai set a goal of having 10,000 patients on Leqembi by the end of March 2024.

8. In February 2023, Biogen provided non-GAAP<sup>1</sup> diluted earnings-per-share (“EPS”) guidance in a range of \$15.00 to \$16.00 per share for full year (“FY”) 2023, and reaffirmed this guidance over multiple quarters.

9. Then, in July 2023, Biogen announced that it would acquire Reata Pharmaceuticals, Inc. (“Reata”) for \$172.50 per share in cash, reflecting an enterprise value of approximately \$7.3 billion (the “Reata Acquisition”). The Reata Acquisition represented yet another important opportunity for Biogen to strengthen its product portfolio and offset declining MS-related treatment sales with the acquisition of Reata’s drug Skyclarys, which had been approved in U.S. as the only treatment indicated for patients with Friedreich’s ataxia. Biogen represented that the Reata Acquisition would only be “slightly” dilutive to Biogen’s non-GAAP diluted EPS in 2023.

10. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Biogen had overstated its efforts to enhance its transparency, corporate governance, and compliance controls and procedures, as well as the efficacy of those controls and procedures; (ii) accordingly, Biogen maintained inadequate compliance controls and procedures in connection with its business operations in foreign countries; (iii) Biogen and/or its employees were engaged in unlawful or

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<sup>1</sup> “GAAP” refers to generally accepted accounting principles, which are a set of accounting rules, standards, and procedures that U.S. public companies must follow when their accountants compile their financial statements.

otherwise improper conduct in several foreign countries; (iv) the foregoing subjected the Company to a heightened risk of governmental and/or regulatory scrutiny and enforcement action, as well as significant legal, financial, and reputational harm; (v) Biogen overstated the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi; (vi) Biogen also downplayed the negative impact that the Reata Acquisition would have on its FY 2023 non-GAAP diluted EPS; (vii) all the foregoing were likely to have a significant negative impact on Biogen's 2023 results; and (viii) as a result, the Company's public statements were materially false and misleading at all relevant times.

11. On November 8, 2023, Biogen announced its third quarter ("Q3") 2023 results, including negatively revised non-GAAP diluted EPS guidance for FY 2023 in a range of \$14.50 to \$15.00 per share, significantly below its previous guidance of FY 2023 non-GAAP diluted EPS of \$15.00 to \$16.00 per share, citing approximately \$0.75 of dilution from the Reata Acquisition.

12. On this news, Biogen's stock price fell \$13.92 per share, or 5.67%, to close at \$231.69 per share on November 8, 2023.

13. On January 8, 2024, Biogen's CEO Defendant Christopher A. Viehbacher ("Viehbacher") attended the J.P. Morgan 42nd Annual Healthcare Conference (the "J.P. Morgan Conference"). While speaking at the conference, Defendant Viehbacher discussed challenges with the launch of Leqembi and walked back prior expectations of having 10,000 patients on the drug by the end of March 2024.

14. As the market digested this news, Biogen's stock price fell \$10.77 per share, or 4.17%, over three consecutive trading days to close at \$247.21 per share on January 11, 2024.

15. On January 31, 2024, Biogen announced that it was discontinuing development and commercialization of Aduhelm and “has recorded a one-time charge of approximately \$60 million related to close out costs for the program in the fourth quarter of 2023.”

16. On February 6, 2024, news reports emerged that Eisai was facing challenges with the launch of Leqembi and that only 2,000 patients in the U.S. had been administered the drug.

17. As the market fully digested this news, Biogen’s stock price fell \$5.01 per share, or 2.04%, to close at \$240.54 per share on February 7, 2024.

18. Then, on February 13, 2024, Biogen issued a press release announcing its fourth quarter (“Q4”) and FY 2023 results, including Q4 non-GAAP EPS of \$2.95, missing consensus estimates by \$0.23, and Q4 revenue of \$2.4 billion, missing consensus estimates by \$60 million and representing a 5.5% year-over-year (“Y/Y”) decline. The Company disclosed that Q4 “GAAP and Non-GAAP diluted EPS [was] negatively impacted by \$0.35 related to [the] previously disclosed closeout costs for ADUHELM[.]” Moreover, on a subsequent conference call to discuss these results with investors and analysts, Defendant Viehbacher confirmed that “we’ve got approximately 2,000 patients on [Leqembi] at the moment” and that “we have an indication that there are about 3,800 patients as of last week on the registry”—a far-cry from the 10,000-patient goal set by the Company and Eisai for the end of following month.

19. The foregoing disappointing results surprised investors and analysts alike, prompting multiple analyst downgrades from major financial firms in addition to a deluge of negative press publications covering these results.

20. Following these developments, Biogen’s stock price fell \$18.09 per share, or 7.39%, to close at \$226.65 per share on February 13, 2024.

21. Finally, on February 14, 2024, Biogen disclosed in an SEC filing that it had received a subpoena from the DOJ “seeking information relating to [Biogen’s] business operations in several foreign countries” and that “[t]he Company is also providing information relating to [its] business operations in several foreign countries to the SEC.”

22. On this news, Biogen’s stock price fell \$5.91 per share, or 2.61%, to close at \$220.74 per share on February 14, 2024.

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

### **JURISDICTION AND VENUE**

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

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

26. 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. § 1391(b). Plaintiff is a resident of this Judicial District, and a substantial part of the property that is the subject of this action is thus situated in this Judicial District. Moreover, pursuant to Biogen’s most recent annual report on Form 10-K, as of February 12, 2024, the Company had over 145 million shares of its common stock outstanding. Biogen’s common stock trades on the Nasdaq Global Select Market (“NASDAQ”). Accordingly, in addition

to Plaintiff, there are presumably hundreds, if not thousands, of investors in Biogen's securities located in the U.S., some of whom, like Plaintiff, undoubtedly reside in this Judicial District.

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

### **PARTIES**

28. Plaintiff, as set forth in the attached Certification, acquired Biogen securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures. Plaintiff is a resident of Jefferson County, Colorado, which is located in this Judicial District.

29. Defendant Biogen is a Delaware corporation with principal executive offices located at 225 Binney Street, Cambridge, Massachusetts 02142. Biogen's common stock trades in an efficient market on the NASDAQ under the ticker symbol "BIIB."

30. Defendant Viehbacher has served as Biogen's President and CEO since November 14, 2022.

31. Defendant Michel Vounatsos ("Vounatsos") served as Biogen's CEO from before the start of the Class Period to November 14, 2022.

32. Defendant Michael R. McDonnell ("McDonnell") has served as Biogen's Chief Financial Officer at all relevant times.

33. Defendants Viehbacher, Vounatsos, and McDonnell are collectively referred to herein as the "Individual Defendants."



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

35. Biogen and the Individual Defendants are collectively referred to herein as “Defendants.”

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

36. Biogen is a global biopharmaceutical company that discovers, develops, and delivers therapies for people living with serious and complex diseases worldwide. The Company operates in various countries throughout the Americas, Europe, and Asia.

37. Biogen’s products include, among others, Leqembi and Aduhelm for the treatment of AD, as well as various drugs for the treatment of MS. Biogen’s sales of its MS-related products have historically accounted for the majority of the Company’s product revenues. However, in recent years, increased competition from generic biosimilars of Biogen’s MS-related products have eroded those products’ revenue growth and led to declining sales. As a result, the Company

has increasingly focused on developing new products to bolster its revenues. Accordingly, because AD-related treatments represented a lucrative market for Biogen, the Company's AD-related products were particularly important to Defendants and investors throughout the Class Period.

38. In 2021, in a major set-back to the Company's development of AD treatments, Biogen was mired in controversy after investigative reports revealed that the Company had engaged in potentially improper communications with representatives of the FDA to win regulatory approval of Aduhelm for the treatment of AD, despite concerns regarding, *inter alia*, the drug's safety and efficacy. Biogen and the FDA's communications and conduct have been the subject of investigations by the FTC, SEC, multiple Congressional Committees, and the Office of the Inspector General of U.S. Department of Health and Human Services.

39. Nor were the foregoing investigations the only source of controversy for Biogen. Separately, in 2022, the DOJ announced that Biogen had agreed to pay \$900 million to settle allegations that it had caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce them to prescribe the Company's MS-related drugs.

40. Following these controversies, Biogen embarked on a campaign to purportedly enhance its transparency, corporate governance, and compliance controls and procedures. Among other things, the Company replaced its CEO in November 2022 and has since released compliance, corporate responsibility, and ESG reports touting the Company's purportedly enhanced compliance and governance practices.

41. Moreover, the controversy surrounding Aduhelm's regulatory approval has, at least in part, led to the drug's failure to gain traction in the lucrative AD-treatment market. Accordingly, Defendants and investors have been particularly focused on the launch of the Company's Leqembi

product, developed in partnership with Eisai, which gained FDA approval as a treatment for AD in 2023.

**Materially False and Misleading Statements Issued During the Class Period**

42. The Class Period begins on February 3, 2022, when Biogen issued a press release during pre-market hours, announcing the Company’s Q4 and FY 2021 results (the “Q4/FY21 Earnings Release”). The Q4/FY21 Earnings Release quoted Defendant Vounatsos, who stated that “Biogen continued to execute well in [Q4] despite the challenges we have faced,” and that “[w]e have introduced the first FDA approved treatment for [AD] in nearly 20 years, and we are engaging with the Centers for Medicare and Medicaid Services with the hope of finding a path for immediate patient access.”

43. With respect to Aduhelm, the Q4/FY21 Earnings Release stated, *inter alia*:

- In [Q4] 2021 Biogen and Eisai presented data at the annual CTAD conference from approximately 7,000 plasma samples from more than 1,800 patients in the ADUHELM Phase 3 clinical trials showed a statistically significant correlation between plasma p-tau reduction and less cognitive and functional decline in [AD]. Reductions in plasma p-tau<sub>181</sub> were also correlated with a lowering of amyloid beta plaque. The analysis of plasma samples was conducted by an independent lab, drawing from the two pivotal ADUHELM Phase 3 EMERGE and ENGAGE trials.

44. Also on February 3, 2022, Biogen filed an annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the quarter and year ended December 31, 2021 (the “2021 10-K”). The 2021 10-K purported to warn of risks that “may,” “might,” or “could” occur “if” Biogen or its employees engaged in wrongful conduct in foreign countries, while downplaying these risks by simultaneously assuring investors that the Company maintained effective compliance controls, policies, and procedures to mitigate these risks, stating, in relevant part:

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight in the U.S. and in foreign jurisdictions, and are subject to change and evolving interpretations, which *could* require us to incur substantial costs associated with compliance or to alter one or more of our business practices . . . . *If* we, or our vendors or donation recipients, are found to fail to comply with relevant laws, regulations or government guidance . . . we *could* be subject to significant fines or penalties. Risks relating to compliance with laws and regulations *may* be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which *may* have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

\* \* \*

Violations of governmental regulation *may* be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs . . . as well as against executives overseeing our business . . . . In addition, legal proceedings and investigations are inherently unpredictable, and large judgments or settlements sometimes occur. While we believe that *we have appropriate compliance controls, policies and procedures in place to comply with the laws or regulations of the jurisdictions in which we operate*, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers *might* violate such laws or regulations. Whether or not we have complied with the law, an investigation or litigation related to alleged unlawful conduct *could* increase our expense, damage our reputation, divert management time and attention and adversely affect our business.

(Emphases added.) Plainly, the foregoing risk warnings were boilerplate, catch-all provisions that were not tailored to Biogen’s actual known risks regarding its failure to maintain adequate compliance controls, policies, and procedures in connection with its business operations in foreign countries, much less Biogen’s actual known risks regarding its or its employees’ illegal, illicit, or otherwise improper activities abroad.

45. Similarly, the 2021 10-K purported to warn of “possible” risks that “may” or “could” occur “if” Biogen or its employees ran afoul of laws prohibiting foreign corrupt practices, while again downplaying these risks by simultaneously assuring investors that the Company

maintained effective compliance controls, policies, and procedures to mitigate these risks, stating, in relevant part:

[O]ur international operations are subject to regulation under U.S. law. For example, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with *may* meet the FCPA’s definition of a foreign government official. Failure to comply with domestic or foreign laws *could* result in various adverse consequences, including *possible* delay in approval or refusal to approve a product, recalls, seizures or withdrawal of an approved product from the market, disruption in the supply or availability of our products or suspension of export or import privileges, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and damage to our reputation . . . . [W]hile we believe that *we have appropriate compliance controls, policies and procedures in place to comply with the FCPA*, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers *might* violate the FCPA and we *might* be held responsible. *If* our employees, agents, distributors, collaborators or third-party providers are found to have engaged in such practices, we *could* suffer severe penalties and *may* be subject to other liabilities, which *could* negatively affect our business, operating results and financial condition.

(Emphases added.) Plainly, these risk warnings, too, were boilerplate, catch-all provisions that were not tailored to Biogen’s actual known risks regarding its failure to maintain adequate compliance controls, policies, and procedures in connection with its business operations in foreign countries, much less Biogen’s actual known risks regarding its or its employees’ illegal, illicit, or otherwise improper activities abroad.

46. Appended as exhibits to the 2021 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein Defendants Vounatsos and McDonnell certified, in relevant part, that the 2021 10-K “does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances

under which such statements were made, not misleading with respect to the period covered by this report;” and that “the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition[ and] results of operations . . . of the [Company] as of, and for, the periods presented in this report[.]”

47. On January 6, 2023, Biogen and Eisai issued a joint press release announcing that the FDA had approved Leqembi as a treatment for AD under the FDA’s Accelerated Approval Pathway. With respect to ensuring patient access to Leqembi, the press release stated, in relevant part:

The Eisai Patient Support Program offers several support programs to help patients and care partners. Dedicated Patient Navigators will work directly with patients and families to navigate treatment and coverage for eligible and appropriate patients and to help with what to expect regarding insurance coverage, co-pay and patient access programs.

\* \* \*

In addition, to support access to LEQEMBI for certain financially disadvantaged patients, Eisai’s Patient Assistance Program (PAP) will provide LEQEMBI at no cost, for eligible uninsured and underinsured patients, including Medicare beneficiaries, who meet financial need and other program criteria.

Eisai looks forward to continuing to engage constructively with various payors, including the Centers for Medicare and Medicaid (CMS), TRICARE, the U.S. Veteran’s Health Administration and private health insurance companies to ensure appropriate beneficiaries have access to this new therapy . . . . Medicaid sole beneficiaries who are diagnosed by a healthcare professional with mild cognitive impairment or mild dementia stage of disease, and with confirmed presence of amyloid plaque in the brain will have access to LEQEMBI under the Medicaid program post accelerated approval, depending on individual state processes.

48. On February 15, 2023, Biogen issued a press release announcing its Q4 and FY 2022 results. That press release provided FY 2023 non-GAAP diluted EPS guidance in a range of \$15.00 to \$16.00 per share, while purporting to warn, in relevant part:

This financial guidance does not include any impact from potential acquisitions or large business development transactions or pending and future litigation, as all are hard to predict, or any impact of potential tax or healthcare reform. Biogen may incur charges, realize gains or losses, or experience other events or circumstances in 2023 that could cause any of these assumptions to change and/or actual results to vary from this financial guidance.

Plainly, the foregoing risk warning was a boilerplate, catch-all provision that was not tailored to Biogen's actual known risks regarding its likely acquisition of Reata and/or other companies to offset its declining MS-related product sales, much less the likely discontinuation of Aduhelm's development and commercialization, and how these factors would negatively impact the Company's 2023 EPS.

49. Also on February 15, 2023, Biogen filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2022 (the "2022 10-K"). The 2022 10-K contained the same boilerplate, catch-all risk warnings as referenced in ¶¶ 44-45, *supra*, purporting to warn of risks that "may", "might", or "could" occur "if" Biogen or its employees engaged in wrongful conduct in foreign countries, as well as "possible" risks that "may" or "could" occur "if" the Company or its employees ran afoul of laws prohibiting foreign corrupt practices, while continuing to downplay these risks by simultaneously assuring investors that the Company maintained effective compliance controls, policies, and procedures to mitigate these risks.

50. Appended as exhibits to the 2022 10-K were substantively the same SOX certifications as referenced in ¶ 46, *supra*, signed by Defendants Viehbacher and McDonnell.

51. On April 25, 2023, Biogen issued a press release announcing its first quarter 2023 results. That press release reaffirmed the Company's FY 2023 non-GAAP diluted EPS guidance in a range of \$15.00 to \$16.00 per share, while containing the same boilerplate, catch-all risk

warning as referenced in in ¶ 48, *supra*, which was not tailored to Biogen’s actual known risks regarding its likely acquisition of Reata and/or other companies to offset its declining MS-related product sales, much less the likely discontinuation of Aduhelm’s development and commercialization, and how these factors would negatively impact the Company’s 2023 EPS.

52. On May 1, 2023, Biogen issued a press release announcing the publication of its “2022 ESG Report,” which purported to “support[] Biogen’s business goals by sharing our corporate responsibility story, disclosing key [ESG] data and providing updated progress against our targets and commitments.”

53. The 2022 ESG Report contained a letter from Defendant Viehbacher, which stated, in relevant part:

For decades, Biogen has been committed to corporate responsibility and, every day, we are working diligently to build upon our long-held foundation of responding appropriately to emerging stakeholder expectations and industry trends to deliver benefits for patients and communities.

\* \* \*

I want to underscore my commitment – reflected in this report – to continuing to advance Biogen’s culture of transparency and disclosure so that our stakeholders, including our employees, patients, investors, partners and communities, have access to reliable data-driven information about all the dimensions of our business.

54. The 2022 ESG Report also touted Biogen’s engagement with “[i]nvestors, analysts and ratings agencies through [*inter alia*] . . . our transparent responses to inquiries from organizations like S&P Global, JUST Capital and others.”

55. In addition, the 2022 ESG Report contained a section entitled “Operating responsibly,” which stated, in relevant part:

Maintaining high standards for corporate responsibility helps us deliver on our purpose and on advancing a healthier, more sustainable and equitable world.



## Advancing an ethical culture

Every action we take, from pioneering new therapies to promoting health equity, is guided by our unwavering commitment to integrity through:

- **Biogen’s credo** – Caring Deeply. Working Fearlessly. Changing Lives.™
- **Biogen Elements** – the foundation of our culture. Just as the periodic table reflects the elements of our universe, the Biogen Elements include pioneering spirit, strong ethics, personal accountability, inclusivity, agility and unwavering customer focus.
- **Code of Business Conduct** – which includes eight Ethical Principles and applies to all Biogen employees, agents and consultants acting on behalf of Biogen and our Affiliates worldwide.

We see these commitments as key enablers of Biogen’s business, and in honoring them, we foster an environment of trust, honesty and transparency while ensuring appropriate confidentiality.

(Emphases in original.)

56. With respect to Biogen’s purportedly robust global compliance policies and procedures, the 2022 ESG Report stated, in relevant part:

Compliance with our Code of Business Conduct, Ethical Principles and the law is mandatory for all employees and a priority of our leaders, without exception.

At the enterprise level, we monitor and address compliance issues very closely. We have more than 20 full-time compliance officers who are embedded with the businesses globally. They use advanced artificial intelligence and other tools and technology to identify and address potential issues.

We also require every employee to report actual or suspected violations of the law or the Code of Business Conduct either to their manager, to a compliance officer or through an anonymous 24/7 helpline . . . . All claims of misconduct . . . are thoroughly investigated.

57. On July 6, 2023, Biogen and Eisai issued a joint press release (the “July 6, 2023 Press Release”) announcing that the FDA had granted traditional approval for Leqembi for the

treatment of AD. The July 6, 2023 Press Release largely touted the broad coverage of, as well as ease of access to, Leqembi. For example, the July 6, 2023 Press Release stated, *inter alia*:

Importantly, following FDA’s traditional approval of LEQEMBI, CMS confirmed that broader coverage of LEQEMBI is now available and released more details on the registry, including the easy-to-use data submission process. The CMS-facilitated registry is now available for healthcare professionals to submit required patient data to CMS. Eisai is pleased that Medicare will cover this important therapy for appropriate patients. This will facilitate reimbursement for and access to LEQEMBI across a broad range of healthcare settings in the [U.S.].

\* \* \*

Eisai is committed to ensuring that appropriate patients have access to LEQEMBI and has established a Patient Assistance Program to provide LEQEMBI at no cost, for eligible uninsured and underinsured patients, including Medicare beneficiaries, who meet financial need and other program criteria. Additionally, Eisai offers patient support for improving access through LEQEMBI Patient Navigators, who will provide information about accessing LEQEMBI, help patients and their families understand their insurance coverage and options, and identify financial support programs for eligible patients.

58. In addition, the July 6, 2023 Press Release quoted Eisai’s CEO, who stated, in relevant part, that “[w]e continue to work to create broad and simple access to LEQEMBI for patients and to support diagnosis and treatment at the early stage of the disease.”

59. The July 6, 2023 Press Release also quoted Defendant Viehbacher, who assured investors that “[o]ur focus is now on the path forward, working alongside Eisai with the goal of making LEQEMBI accessible to eligible patients as soon as possible.”

60. On July 25, 2023, Biogen issued a press release announcing its second quarter 2023 results. That press release reaffirmed the Company’s FY 2023 non-GAAP diluted EPS guidance in a range of \$15.00 to \$16.00 per share, while containing the same boilerplate, catch-all risk warning as referenced in ¶ 48, *supra*, which was not tailored to Biogen’s actual known risks regarding its likely acquisition of Reata and/or other companies to offset its declining MS-related

product sales, much less the likely discontinuation of Aduhelm’s development and commercialization, and how these factors would negatively impact the Company’s 2023 EPS.

61. On July 28, 2023, Biogen issued a press release (the “July 28, 2023 Press Release”) announcing the Reata Acquisition. The July 28, 2023 Press Release touted that the “[p]roposed acquisition represents meaningful step forward in Biogen’s strategy for sustainable growth, adding a highly complementary innovative product in an area of high unmet medical need”; and that the acquisition is “[e]xpected to be significantly accretive to Biogen’s Non-GAAP diluted EPS beginning in 2025[.]”

62. The July 28, 2023 Press Release also stated, in relevant part:

The acquisition of Reata is expected to be *slightly* dilutive to Biogen’s Non-GAAP diluted [EPS] in 2023, roughly neutral in 2024, and significantly accretive beginning in 2025, inclusive of associated transaction costs. Biogen plans to update its [FY] 2023 Financial Guidance in conjunction with its [Q3] 2023 earnings release.

(Emphasis added.)

63. Upon information and belief, also in July 2023, Biogen published a document entitled “Comprehensive Compliance Program” (the “2023 Compliance Report”) on the “Governance Documents” section of its website. The 2023 Compliance Report stated, *inter alia*:

Biogen is committed to . . . maintaining the highest level of integrity and ethical behavior in the conduct of our business. To this end, Biogen’s Code of Business Conduct is available to the public through its posting on this website.

To conduct our business with integrity and ethically, Biogen has established and maintains a compliance program. This program has been developed in accordance with the laws applicable to our industry and the “Program Guidance for Pharmaceutical Manufacturers” published by the Office of the Inspector General of the U.S. Department of Health and Human Services (“OIG Guidance”). Moreover, the Pharmaceutical Research and Manufacturers of America, the pharmaceutical industry’s trade group, voluntarily adopted its own “Code on Interactions with Healthcare Professionals” known as the “PhRMA Code.” Biogen’s compliance

program requires compliance with the PhRMA Code, which addresses topics such as informational presentations by the Company, third party continuing education and professional meetings, use of consultants and speakers, as well as restrictions on the provision of gifts and financial incentives to healthcare professionals.

64. The 2023 Compliance Report also stated that Biogen’s compliance program includes, among other mechanisms, the “[u]se of audits and other techniques to monitor compliance and identify and address of [*sic*] risk”; “[e]nforcement of compliance obligations through guidelines that include penalties for noncompliance”; and “[m]echanisms to promptly and properly investigate and respond to reports of noncompliance, including processes to initiate corrective measures and to report offenses to the relevant government authorities where appropriate”; all of which assured investors that the Company had an effective compliance program in place to monitor, identify, enforce, and correct instances of non-compliance and report such instances to relevant authorities.

65. Moreover, the 2023 Compliance Report represented that, “as of July 1, 2023, Biogen is in material compliance with its Comprehensive Compliance Program[.]”

66. On September 26, 2023, Biogen issued a press release announcing that it had completed its acquisition of Reata, stating, in relevant part:

Biogen anticipates significant synergies with its existing rare disease portfolio and plans to update its [FY] 2023 Financial Guidance in conjunction with its [Q3] 2023 earnings release. The acquisition of Reata is expected to be *slightly* dilutive to Biogen’s Non-GAAP diluted [EPS] in 2023, roughly neutral in 2024, and significantly accretive beginning in 2025, inclusive of associated transaction costs.

(Emphasis added.)

67. The statements referenced in ¶¶ 42-66 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about Biogen’s business, operations, and compliance policies. Specifically, Defendants made

false and/or misleading statements and/or failed to disclose that: (i) Biogen had overstated its efforts to enhance its transparency, corporate governance, and compliance controls and procedures, as well as the efficacy of those controls and procedures; (ii) accordingly, Biogen maintained inadequate compliance controls and procedures in connection with its business operations in foreign countries; (iii) Biogen and/or its employees were engaged in unlawful or otherwise improper conduct in several foreign countries; (iv) the foregoing subjected the Company to a heightened risk of governmental and/or regulatory scrutiny and enforcement action, as well as significant legal, financial, and reputational harm; (v) Biogen overstated the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi; (vi) Biogen also downplayed the negative impact that the Reata Acquisition would have on its FY 2023 non-GAAP diluted EPS; (vii) all the foregoing were likely to have a significant negative impact on Biogen's 2023 results; and (viii) as a result, the Company's public statements were materially false and misleading at all relevant times.

### **The Truth Begins to Emerge**

68. On November 8, 2023, during pre-market hours, Biogen issued a press release (the "Q3 2023 Earnings Release") announcing its Q3 2023 results. That press release updated the Company's non-GAAP diluted EPS guidance for FY 2023 to a range of \$14.50 to \$15.00 per share, significantly below its previously reaffirmed guidance range of \$15.00 to \$16.00 per share, citing approximately \$0.75 of dilution from the Reata Acquisition.

69. On this news, Biogen's stock price fell \$13.92 per share, or 5.67%, to close at \$231.69 per share on November 8, 2023. Despite this decline in the Company's stock price, Biogen securities continued trading at artificially inflated prices throughout the remainder of the

Class Period because of Defendants' continued misstatements and omissions regarding the Company's compliance controls and procedures, as well as the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi.

70. For example, the Q3 2023 Earnings Release provided the same boilerplate, catch-all risk warning as referenced in ¶ 48, *supra*, which was not tailored to Biogen's actual known risks regarding its likely discontinuation of Aduhelm's development and commercialization, including tens-of-millions of dollars in associated close-out costs, much less how this would impact the Company's EPS for 2023.

71. Also on November 8, 2023, Biogen held a conference call (the "Q3 2023 Earnings Call") with investors and analysts to discuss the Company's Q3 results. In his prepared remarks on the Q3 2023 Earnings Call, Defendant Viehbacher expressed his confidence in having 10,000 patients on Leqembi by the end of March 2024, stating, *inter alia*:

So, of course, we have an aim of getting to 10,000 patients by the end of March. We're at 800 now. What gives us the confidence that we think we can get there? I think we have a number of greenshoots here, signs of progress.

The first is, as we look at our internal metrics of intent to treat and patient demand, we are seeing all of those things progress extremely nicely. The FDA not only provided traditional approval, but CMS actually moved very quickly, the day of traditional approval, as they promised. They actually have provided reimbursement and the patient registry has so far from what we hear from the market been relatively easy to use.

\* \* \*

I think one of the most interesting things is we've got 60% of the top 100 targeted IDMs now having P&T [pharmacy and therapeutics] approval. And one of the things that really gives me a lot of inspiration is usually these P&T committees meet twice a year, but a number of them actually have organized special meetings just for LEQEMBI and not wait until the next meeting. And that says to me that

there's a recognition of the importance of this treatment and being able to get patients on treatment.

\* \* \*

So now, of course, we're also looking at executing on geographic expansion. We've had the recent approval of Japan and I'm traveling to Japan early in the new year to be with my friend and colleague, the CEO of Eisai to launch LEQEMBI in Japan. And of course, we've got global filings under review in the EU, China and 10 other markets.

So this is one where we're going to have to be patient, but all the signs are green at this moment. And for us, internally, we see a launch that is on track.

72. On December 12, 2023, Biogen and Eisai issued a joint press release announcing the anticipated launch of Leqembi for the treatment of AD in Japan on December 20, 2023 (the "December 2023 Press Release"). The December 2023 Press Release quoted Eisai's CEO, who stated, in relevant part:

The establishment of an optimal and fast [AD] diagnosis and treatment pathway for patients is a top priority, and close collaboration among the government, dementia specialists, primary care physicians, radiologists, pharmacists, nurses, clinical psychologists, radiology staff, medical office personnel, and caregivers is essential for this purpose. In consideration of the importance of [AD] in Japan, we believe it is imperative that such pathways be established. We are committed to taking this first step towards changing the future of [AD] together with our stakeholders.

73. The December 2023 Press Release also quoted Defendant Viehbacher, who stated, in relevant part:

The availability of LEQEMBI opens a new era in the treatment of [AD] . . . . We will work alongside Eisai to engage the medical community and support the patient journey, especially early diagnosis[.]

74. The statements referenced in ¶¶ 70-73 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about Biogen's business, operations, and compliance policies. Specifically, Defendants made

false and/or misleading statements and/or failed to disclose that: (i) Biogen had overstated its efforts to enhance its transparency, corporate governance, and compliance controls and procedures, as well as the efficacy of those controls and procedures; (ii) accordingly, Biogen maintained inadequate compliance controls and procedures in connection with its business operations in foreign countries; (iii) Biogen and/or its employees were engaged in unlawful or otherwise improper conduct in several foreign countries; (iv) the foregoing subjected the Company to a heightened risk of governmental and/or regulatory scrutiny and enforcement action, as well as significant legal, financial, and reputational harm; (v) Biogen overstated the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi; (vi) all the foregoing were likely to have a significant negative impact on Biogen's 2023 results; and (vii) as a result, the Company's public statements were materially false and misleading at all relevant times.

75. On January 8, 2024, Defendant Viehbacher attended the J.P. Morgan Conference. While speaking at the J.P. Morgan Conference, Defendant Viehbacher discussed challenges associated with the launch of Leqembi and walked back prior expectations of having 10,000 patients on the drug by the end of March 2024, stating, in relevant part:

Remember, the 10,000 was really designed to try to give people some sort of milestone, because there are no real analogues for this launch. I haven't found a decent analog anywhere. So, what I think we were trying to say is, this isn't going to be 100,000 patients, but it is not going to be 1,000 either. So that is a trajectory. And I think where we are right now, there is nothing that we are going to do that's going to change us on the trajectory. We will get there. We don't get there. I think everything we are seeing. There is no reason to say that, we can't get there.

But again, the data were kind of choppy in December. So, for me, I am really looking for the January data. But where we are right now is, 10,000 isn't really what we are interested anymore. It's how do we now get to the 100,000? And so that's where we are focused. But you can't get to the 100,000 unless you have really



got this go-to-market strategy really nailed down. And I think we are increasingly confident in that model.

76. As the market and investors digested this news, Biogen's stock price fell \$10.77 per share, or 4.17%, over three consecutive trading days to close at \$247.21 per share on January 11, 2024. Despite this decline in the Company's stock price, Biogen securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding the Company's compliance controls and procedures, as well as the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi.

77. For example, at the J.P. Morgan Conference, Defendant Viehbacher continued to assert that the launch of Leqembi and patient access to the drug remained relatively on track, stating, *inter alia*:

So, numbers of PET scans are going up. When we talk to people who are providing the PET scans, they're seeing lots of activity. People who are providing the blood-based biomarkers and diagnostics are seeing increased activity. We're seeing a significant increase in the numbers of new patient starts on the registry. And in terms of reimbursement, CMS said, "Okay, we're now changing and clarifying the reimbursement for PET scans." But that has to be pulled through by the dozen or so max that are out there. And they typically don't move that quickly, but they have moved faster than anybody has ever seen before.

A lot of the IDMs were on formulary, and they have done out of cycle, P&T committee meetings because they see it as an urgency. We certainly have patients waiting for treatment. So, the real job is just establishing the care, pathways getting the policies in place and the blocking and tackling of being able to process the patients. So, I think we're feeling pretty good. I'm looking forward to seeing how the January sales play out. A lot of positive data in December, but December is kind of a funny month with the holiday schedule, but I think we're certainly seeing an awful lot of tremendous progress on LEQEMBI.

\* \* \*

We're not seeing any capacity constraints on PET scans nor on MRIs nor on infusion centers for the moment. So, I think that will flex.

So largely, it is really around the care pathways and just establishing those. And that increases every day when the number of centers ordering from, when we did Q3 earnings to now was up 37%, for example.

\* \* \*

[I]t's starting to broaden out. There's still - we've probably got about a target of 10,000, and we're working our way through that.

78. On January 9, 2024, Biogen and Eisai issued a joint press release announcing the approval of Leqembi for the treatment of AD in China, stating, in relevant:

Eisai estimates that there will be 17 million patients with MCI or mild dementia due to AD in China in 2024, which is expected to increase with the aging of the population. Eisai will distribute the product in China and will conduct information provision activities through specialized Medical Representatives. Moving forward, Eisai will focus on AD awareness via omnichannel systems and collaborate with specialists to improve the diagnostic environment, including blood-based biomarkers. In addition, by utilizing online health platform for the elderly "Yin Fa Tong"\*\*, which is already being accessed by a certain number of users and helping provide treatments, Eisai is providing a one-stop service that promotes early consultation by referring patients to medical specialists and follow-up after treatment. In addition, Eisai will work to improve access environments including the development of insurance programs for AD in collaboration with insurance companies. Through these efforts, Eisai will accelerate the construction of a simple patient journey in China.

79. The statements referenced in ¶¶ 77-78 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about Biogen's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Biogen had overstated its efforts to enhance its transparency, corporate governance, and compliance controls and procedures, as well as the efficacy of those controls and procedures; (ii) accordingly, Biogen maintained inadequate compliance controls and procedures in connection with its business

operations in foreign countries; (iii) Biogen and/or its employees were engaged in unlawful or otherwise improper conduct in several foreign countries; (iv) the foregoing subjected the Company to a heightened risk of governmental and/or regulatory scrutiny and enforcement action, as well as significant legal, financial, and reputational harm; (v) Biogen overstated the strength of its AD-related product portfolio, including the Company's and Eisai's efforts and success in launching and providing access to Leqembi; (vi) all the foregoing were likely to have a significant negative impact on Biogen's 2023 results; and (vii) as a result, the Company's public statements were materially false and misleading at all relevant times.

### **The Truth Fully Emerges**

80. On January 31, 2024, Biogen issued a press release announcing that it would discontinue development and commercialization of Aduhelm and that it had recorded \$60 million in associated close-out costs, stating, in relevant part:

Biogen . . . plans to reprioritize its resources in [AD] . . . . The company will discontinue the development and commercialization of ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use and will terminate the ENVISION clinical study.

\* \* \*

In January 2023, Biogen began a strategic review of its research and development efforts, including seeking potential partners or external financing for ADUHELM, as part of a focus on prioritizing the company's portfolio. During this process, Biogen considered the time and investment required for the post-marketing confirmatory ENVISION study and the likely advancements in the field by the time of potential ADUHELM FDA traditional approval. Despite an extensive process, the company did not identify potential strategic partners or external financing.

Biogen has recorded a one-time charge of approximately \$60 million related to close out costs for the program in the fourth quarter of 2023.

81. On February 6, 2024, news reports emerged that Eisai was facing challenges with the launch of Leqembi and that only 2,000 patients in the U.S. had been administered the drug. For example, an article published by *Bloomberg* that day, entitled “Eisai’s New Alzheimer’s Drug Is Falling Short of US Target,” stated, in relevant part:

Eisai Co. said its breakthrough Alzheimer’s drug has been administered to 2,000 patients in the US, falling behind a target of 10,000 people by the end of March.

The medicine is approved for use in three countries so far — the US, Japan and China. About 100 people have used the drug, named Leqembi, in Japan as of Feb. 5, Eisai said in documents released along with earnings on Tuesday. The company also said it’s preparing to start selling the drug in China in the second quarter of the 2024 fiscal year.

82. As the market fully digested this news, Biogen’s stock price fell \$5.01 per share, or 2.04%, to close at \$240.54 per share on February 7, 2024.

83. On February 13, 2024, during pre-market hours, Biogen issued a press release announcing its Q4 and FY 2023 results (the “Q4/FY 2023 Earnings Release”), including Q4 non-GAAP EPS of \$2.95, missing consensus estimates by \$0.23, and Q4 revenue of \$2.4 billion, missing consensus estimates by \$60 million and representing a 5.5% Y/Y decline. The Q4/FY 2023 Press Release specifically attributed Biogen’s disappointing Q4 EPS results to its discontinuation of Aduhelm, disclosing that Q4 “GAAP and Non-GAAP diluted EPS [was] negatively impacted by \$0.35 related to [the] previously disclosed closeout costs for ADUHELM,” with Q4 “2023 GAAP and Non-GAAP R&D [research and development] expense includ[ing] . . . approximately \$60 million in close out costs related to ADUHELM.”

84. That same day, also during pre-market hours, Biogen held a conference call (the “Q4/FY 2023 Earnings Call”) with investors and analysts to discuss the Company’s Q4 and FY 2023 results. During his prepared remarks on the Q4/FY 2023 Earnings Call, Defendant

Viehbacher confirmed that “we’ve got approximately 2,000 patients on [Leqembi] at the moment” and that “we have an indication that there are about 3,800 patients as of last week on the registry”—a far-cry from the 10,000-patient goal set by the Company and Eisai for the end of following month.

85. During the question-and-answer portion of the Q4/FY 2023 Earnings Call, in response to an analyst request for additional color on “the bottlenecks on the LEQEMBI launch,” Defendant Viehbacher responded, in relevant part:

The bottlenecks, I still -- if you think about it, if the data from the patient registries are accurate, and again, we don’t have direct access to that, but it suggests that we’ve got almost twice as many people on the registry as we do on treatment.

And so that says that in addition to the bottleneck of getting into the neurologist, that there’s -- when you get to the registry, you’ve got a clear intent to prescribe, because on the registry, at least for CMS, you have to describe how you actually validated the diagnosis. So by then, you’ve triaged the patient, you’ve done either the PET scan or the CSF markers, and you’re looking for reimbursement.

And what we’re hearing a little bit is, is that there is some challenge in just scheduling the first MRI, because when we initiate the infusion, you have to have the first MRI within the first two weeks. So people don’t want to initiate the infusion until they’ve got that MRI scheduled. And the MRI -- there isn’t an MRI capacity constraint per se, but you are looking for a specific date, and then you have to back up the infusion. So there’s just, I think, until people get the hang of this, getting all that coordination, I think that seems to be where the -- where one of the bottlenecks is.

86. Following the Q4/FY 2023 Earnings Release and Q4/FY 2023 Earnings Call, multiple analysts downgraded or else cut their price target on Biogen’s stock. As reported by *Bloomberg*, **fourteen** analysts cut their price targets on Biogen stock by an average of 5.7%. Notably, J.P. Morgan cut its price target on Biogen stock to \$270 from \$290, and Wells Fargo Securities downgraded its recommendation on Biogen stock to “Equal Weight” from “Overweight.”

87. Moreover, the same day as the Q4/FY 2023 Earnings Release and Q4/FY 2023 Earnings Call, multiple news outlets reported on Biogen’s disappointing Q4 and FY 2023 results—in particular, in addition to the impacts of poor MS-related product sales, the slow ramp-up of patients taking Leqembi and Aduhelm’s close-out costs. For example, an article published by *Bloomberg* on February 13, 2024, entitled “Biogen Plunges as Alzheimer Drug’s Slow Uptake Signals Reset,” stated, in relevant part:

Biogen Inc. fell the most in two years as its latest foray into [AD] got off to a slow start, suggesting a long road to growth for the biotechnology giant.

Just 2,000 patients have been treated so far with Leqembi, Biogen said Tuesday, a warning that the Alzheimer’s drug developed with Eisai Co. may miss its target of 10,000 recipients by the end of March.

Wall Street needs to reset its projections for the new drug, Wedbush Securities analyst Laura Chico said in a note, and Biogen’s “turnaround story remains a work in progress.” The shares fell as much 7.2% as of noon in New York, the most intraday since January 2022.

After Biogen’s Aduhelm failed to gain traction with Alzheimer’s patients and payers, [Defendant] Viehbach is focusing on Leqembi to replace sales of its [MS] treatments. MS drugs were long the company’s mainstay and are now succumbing to cheaper alternatives.

88. Similarly, an article published by *Investopedia* on February 13, 2024, entitled “Biogen Tumbles as Drug Closeout Costs, Multiple Sclerosis Medicine Sales Weigh on Profit,” reported, *inter alia*, that “Biogen (BIIB) shares fell over 5% in early trading Tuesday after the biotech firm posted weaker-than-expected results, weighed down by costs for discontinuing a controversial Alzheimer’s drug, Aduhelm, and slowing sales of [MS] medicines.” The article observed that “EPS was negatively impacted by 35 cents, related to previously-disclosed closeout expenses for Aduhelm,” “which faced criticism about its effectiveness and costs.”

89. Likewise, an article published by *Reuters* on February 13, 2024, entitled “Biogen sees flat 2024 sales, pick up in Alzheimer’s drug demand,” stated, in relevant part:

Since CEO [Defendant] Viehbacher took the helm at Biogen in late 2022, the company has cut jobs, acquired rare disease drugmaker Reata for \$6.5 billion and abandoned controversial Alzheimer’s drug Aduhelm, as he works to steer the company back to growth.

Biogen is counting on newer medicines, including a second approved Alzheimer’s drug Leqembi developed with Japanese partner Eisai, to drive growth for the next few years.

Based on data from an Alzheimer’s Association patient registry, Biogen estimates that as of last week there were 3,800 patients prescribed or close to being prescribed Leqembi, an increase of about 56% from December.

\* \* \*

Wall Street analysts no longer expect the drug to hit a target of 10,000 patients by March after Eisai last week said there were only 2,000 patients taking Leqembi so far.

\* \* \*

Biogen said it and Eisai plan to increase the U.S. Leqembi sales force by 30% as they seek to boost sales.

“That’s a meaningful expansion. You wouldn’t be doing that if you felt that the product was going to make \$10 million in a quarter,” said William Blair analyst Myles Minter[.]

“So the debate is all about: is Leqembi that massive \$6 billion plus product, or is it something that’s going to remain niche,” Minter said in an interview.

90. Following the foregoing disclosures, analyst downgrades and price cuts, and negative news reports, Biogen’s stock price fell \$18.09 per share, or 7.39%, to close at \$226.65 per share on February 13, 2024.

91. Then, on February 14, 2024, Biogen filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023. Therein, the Company disclosed, in relevant part:

The Company has received a subpoena from the DOJ seeking information relating to our business operations in several foreign countries. The Company is also providing information relating to our business operations in several foreign countries to the SEC.

92. News outlets quickly reported on the foregoing disclosure. For example, also on February 14, 2024, *Reuters* published an article entitled "Biogen gets DOJ subpoena on business operations in foreign countries," stating, in relevant part:

Biogen . . . has received a subpoena from the [DOJ] seeking information relating to the company's business operations in several foreign countries, the drugmaker disclosed in a regulatory filing on Wednesday.

Biogen also said it is providing information on foreign business operations to the [SEC].

When contacted by Reuters, the company did not disclose details on the subpoena and said it "does not comment on investigations".

The DOJ and the SEC did not immediately respond to Reuters' requests for comments.

93. On this news, Biogen's stock price fell \$5.91 per share, or 2.61%, to close at \$220.74 per share on February 14, 2024.

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



### **SCIENTER ALLEGATIONS**

95. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

96. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Biogen securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

97. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Biogen securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Biogen or its transfer agent and may be notified of the

pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

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

99. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Biogen;
- whether the Individual Defendants caused Biogen to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Biogen securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

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

102. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Biogen securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Biogen securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

103. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

104. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*

*United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

### **COUNT I**

#### **(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)**

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

106. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

107. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and 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 employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Biogen securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Biogen securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

108. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly

and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Biogen securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Biogen's finances and business prospects.

109. By virtue of their positions at Biogen, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

110. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Biogen, the Individual Defendants had knowledge of the details of Biogen's internal affairs.

111. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Biogen. As officers and/or directors of a publicly-held company, the Individual Defendants had a

duty to disseminate timely, accurate, and truthful information with respect to Biogen's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Biogen securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Biogen's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Biogen securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

112. During the Class Period, Biogen securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Biogen securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Biogen securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Biogen securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

113. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

114. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

## **COUNT II**

### **(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

115. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

116. During the Class Period, the Individual Defendants participated in the operation and management of Biogen, and conducted and participated, directly and indirectly, in the conduct of Biogen's business affairs. Because of their senior positions, they knew the adverse non-public information about Biogen's misstatement of income and expenses and false financial statements.

117. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Biogen's financial condition and results of operations, and to correct promptly any public statements issued by Biogen which had become materially false or misleading.

118. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Biogen disseminated in the marketplace during the Class Period concerning Biogen's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Biogen to engage in the wrongful acts complained of herein.

The Individual Defendants, therefore, were “controlling persons” of Biogen within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Biogen securities.

119. Each of the Individual Defendants, therefore, acted as a controlling person of Biogen. By reason of their senior management positions and/or being directors of Biogen, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Biogen to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Biogen and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

120. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Biogen.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.



**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: May 22, 2024