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8 *Counsel for Plaintiff*

9 UNITED STATES DISTRICT COURT  
10 CENTRAL DISTRICT OF CALIFORNIA

11 \_\_\_\_\_, Individually and on behalf  
12 of all others similarly situated,

13 Plaintiff,

14 v.

15 BIOGEN INC., MICHEL  
16 VOUNATSOS, JEFFREY D.  
17 CAPELLO, and MICHAEL R.  
18 MCDONNELL,

19 Defendants.

Case No.

CLASS ACTION COMPLAINT FOR  
VIOLATION OF THE FEDERAL  
SECURITIES LAWS

JURY TRIAL DEMANDED

20  
21 Plaintiff \_\_\_\_\_ (“Plaintiff”), individually and on behalf of all other  
22 persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s  
23 complaint against Defendants (defined below), alleges the following based upon  
24 personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and  
25 belief as to all other matters, based upon, *inter alia*, the investigation conducted by  
26 and through his attorneys, which included, among other things, a review of the  
27

1 Defendants’ public documents, conference calls and announcements made by  
2 Defendants, public filings, wire and press releases published by and regarding  
3 Biogen Inc. (“Biogen” or the “Company”), and information readily obtainable on  
4 the Internet. Plaintiff believes that substantial evidentiary support will exist for the  
5 allegations set forth herein after a reasonable opportunity for discovery.

6 **NATURE OF THE ACTION**

7 1. This is a class action on behalf of persons or entities who purchased or  
8 otherwise acquired publicly traded Biogen securities between October 22, 2019 and  
9 November 6, 2020, inclusive (the “Class Period”). Plaintiff seeks to recover  
10 compensable damages caused by Defendants’ violations of the federal securities  
11 laws under the Securities Exchange Act of 1934 (the “Exchange Act.”

12 **JURISDICTION AND VENUE**

13 2. The claims asserted herein arise under and pursuant to §§10(b) and  
14 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5  
15 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

16 3. This Court has jurisdiction over the subject matter of this action under  
17 28 U.S.C. §1331 and §27 of the Exchange Act.

18 4. Venue is proper in this judicial district pursuant to §27 of the Exchange  
19 Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the alleged misstatements entered  
20 and the subsequent damages took place in this judicial district.

21 5. In connection with the acts, conduct and other wrongs alleged in this  
22 Complaint, Defendants (defined below), directly or indirectly, used the means and  
23 instrumentalities of interstate commerce, including but not limited to, the United  
24 States mail, interstate telephone communications and the facilities of the national  
25 securities exchange.  
26  
27

1 **PARTIES**

2 6. Plaintiff, as set forth in the accompanying Certification, purchased the  
3 Company's securities at artificially inflated prices during the Class Period and was  
4 damaged upon the revelation of the alleged corrective disclosure.

5 7. Defendant Biogen Inc. purports to discover, develop, manufacture, and  
6 deliver therapies for treating neurological and neurodegenerative diseases including  
7 aducanumab (BIIB037) which is an investigational human monoclonal antibody  
8 studied for the treatment of early Alzheimer's disease. Biogen licensed aducanumab  
9 from Neurimmune under a collaborative development and license agreement. Since  
10 October 2017 Biogen and Eisai have collaborated on the development and  
11 commercialization of aducanumab globally.

12 8. Biogen is incorporated in Delaware and its head office is located at 225  
13 Binney Street, Cambridge, MA 02142. Biogen's securities trade on the NASDAQ  
14 Exchange ("NASDAQ") under the ticker symbol "BIIB".

15 9. Defendant Michel Vounatsos ("Vounatsos") has served as the  
16 Company's Executive Officer ("CEO") and as a Director since January 2017.

17 10. Defendant Jeffrey D. Capello ("Capello") served as the Company's  
18 Chief Financial Officer ("CFO") and Executive Vice President from December 2017  
19 to August 2020.

20 11. Defendant Michael R. McDonnell ("McDonnell") has served as the  
21 Company's CFO and Executive Vice President since August 2020.

22 12. Defendants Vounatsos, Capello, and McDonnell are sometimes  
23 referred to herein as the "Individual Defendants."

24 13. Each of the Individual Defendants:

25 (a) directly participated in the management of the Company;

- 1 (b) was directly involved in the day-to-day operations of the Company at  
2 the highest levels;
- 3 (c) was privy to confidential proprietary information concerning the  
4 Company and its business and operations;
- 5 (d) was directly or indirectly involved in drafting, producing, reviewing  
6 and/or disseminating the false and misleading statements and  
7 information alleged herein;
- 8 (e) was directly or indirectly involved in the oversight or implementation  
9 of the Company's internal controls;
- 10 (f) was aware of or recklessly disregarded the fact that the false and  
11 misleading statements were being issued concerning the Company;  
12 and/or  
13
- 14 (g) approved or ratified these statements in violation of the federal  
15 securities laws.

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

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

23 16. The Company and the Individual Defendants are referred to herein,  
24 collectively, as the "Defendants."

25 **SUBSTANTIVE ALLEGATIONS**

26 **Materially False and Misleading Statements**

1           17. On October 22, 2019, Biogen issued a press release entitled “Biogen  
2 Plans Regulatory Filing for Aducanumab in Alzheimer’s Disease Based on New  
3 Analysis of Larger Dataset from Phase 3 Studies” which announced the following,  
4 in relevant part, regarding aducanumab:

5  
6           CAMBRIDGE, Mass. and TOKYO, Oct. 22, 2019 (GLOBE  
7 NEWSWIRE) -- Biogen (Nasdaq: BIIB) and Eisai, Co., Ltd. (Tokyo,  
8 Japan) today announced that, after consulting with the U.S. Food and  
9 Drug Administration (FDA), ***Biogen plans to pursue regulatory  
10 approval for aducanumab, an investigational treatment for early  
11 Alzheimer’s disease (AD). The Phase 3 EMERGE Study met its  
12 primary endpoint showing a significant reduction in clinical decline,  
13 and Biogen believes that results from a subset of patients in the Phase  
14 3 ENGAGE Study who received sufficient exposure to high dose  
15 aducanumab support the findings from EMERGE.*** Patients who  
16 received aducanumab experienced significant benefits on measures of  
17 cognition and function such as memory, orientation, and language.  
18 Patients also experienced benefits on activities of daily living including  
19 conducting personal finances, performing household chores such as  
20 cleaning, shopping, and doing laundry, and independently traveling out  
21 of the home. If approved, aducanumab would become the first therapy  
22 to reduce the clinical decline of Alzheimer’s disease and would also be  
23 the first therapy to demonstrate that removing amyloid beta resulted in  
24 better clinical outcomes.

25           ***The decision to file is based on a new analysis, conducted by Biogen  
26 in consultation with the FDA, of a larger dataset from the Phase 3  
27 clinical studies that were discontinued in March 2019 following a  
28 futility analysis. This new analysis of a larger dataset that includes  
additional data that became available after the pre-specified futility  
analysis shows that aducanumab is pharmacologically and clinically  
active as determined by dose-dependent effects in reducing brain  
amyloid and in reducing clinical decline as assessed by the pre-  
specified primary endpoint Clinical Dementia Rating-Sum of Boxes  
(CDR-SB).*** In both studies, the safety and tolerability profile of  
aducanumab was consistent with prior studies of aducanumab.

1 “With such a devastating disease that affects tens of millions  
2 worldwide, today’s announcement is truly heartening in the fight  
3 against Alzheimer’s. This is the result of groundbreaking research and  
4 is a testament to Biogen’s steadfast determination to follow the science  
5 and do the right thing for patients,” said Michel Vounatsos, Chief  
6 Executive Officer at Biogen. “We are hopeful about the prospect of  
7 offering patients the first therapy to reduce the clinical decline of  
8 Alzheimer’s disease and the potential implication of these results for  
9 similar approaches targeting amyloid beta.”

10 Based on discussions with the FDA, the Company plans to file a  
11 Biologics License Application (BLA) in early 2020 and will continue  
12 dialogue with regulatory authorities in international markets including  
13 Europe and Japan. *The BLA submission will include data from the  
14 Phase 1/1b studies as well as the complete set of data from the Phase  
15 3 studies.*

16 \* \* \*

### 17 **Study Results**

18 EMERGE (1,638 patients) and ENGAGE (1,647 patients) were Phase  
19 3 multicenter, randomized, double-blind, placebo-controlled, parallel-  
20 group studies designed to evaluate the efficacy and safety of two  
21 dosing regimens of aducanumab. These studies were discontinued on  
22 March 21, 2019, following the results of a pre-specified futility  
23 analysis which relied on an earlier and smaller dataset. The futility  
24 analysis was based on data available as of December 26, 2018, from  
25 1,748 patients who had the opportunity to complete the 18-month  
26 study period and predicted that both studies were unlikely to meet  
27 their primary endpoint upon completion. . . .

28 Following the discontinuation of EMERGE and ENGAGE, additional  
data from these studies became available resulting in a larger dataset,  
which included a total of 3,285 patients, 2,066 of whom had the  
opportunity to complete the full 18 months of treatment. *A new  
extensive analysis of this larger dataset showed a different outcome*

1 *than the outcome predicted by the futility analysis.* Specifically, the  
2 new analysis of this larger dataset showed EMERGE to be statistically  
3 significant on the pre-specified primary endpoint (P=0.01). *Biogen*  
4 *believes that data from a subset of ENGAGE support the findings*  
5 *from EMERGE, though ENGAGE did not meet its primary endpoint.*  
6 Biogen consulted with external advisors and the FDA on these different  
7 results and their implications.

8 *“This large dataset represents the first time a Phase 3 study has*  
9 *demonstrated that clearance of aggregated amyloid beta can reduce*  
10 *the clinical decline of Alzheimer’s disease, providing new hope for*  
11 *the medical community, the patients, and their families,”* said Dr.  
12 Anton Porsteinsson, William B. and Sheila Konar Professor of  
13 Psychiatry, Neurology and Neuroscience, director of the University of  
14 Rochester Alzheimer’s Disease Care, Research and Education Program  
15 (AD-CARE), and principal investigator. “There is tremendous unmet  
16 medical need, and the Alzheimer’s disease community has been waiting  
17 for this moment. I commend Biogen, the FDA, the medical community,  
18 and the patients and their study partners for their persistence in working  
19 to make today’s announcement a reality.”

20 *In EMERGE, which met its pre-specified primary endpoint in the new*  
21 *analysis,* patients treated with high dose aducanumab showed a  
22 significant reduction of clinical decline from baseline in CDR-SB  
23 scores at 78 weeks (23% versus placebo, P=0.01). In EMERGE,  
24 patients treated with high dose aducanumab also showed a consistent  
25 reduction of clinical decline as measured by the pre-specified  
26 secondary endpoints: the Mini-Mental State Examination (MMSE;  
27 15% versus placebo, P=0.06), the AD Assessment Scale-Cognitive  
28 Subscale 13 Items (ADAS-Cog 13; 27% versus placebo, P=0.01), and  
the AD Cooperative Study-Activities of Daily Living Inventory Mild  
Cognitive Impairment Version (ADCS-ADL-MCI; 40% versus  
placebo, P=0.001). Imaging of amyloid plaque deposition in EMERGE  
demonstrated that amyloid plaque burden was reduced with low and  
high dose aducanumab compared to placebo at 26 and 78 weeks  
(P<0.001). Additional biomarker data of tau levels in the cerebrospinal  
fluid supported these clinical findings. *Biogen believes that data from*

1 *patients in ENGAGE who achieved sufficient exposure to high dose*  
2 *aducanumab supported the findings of EMERGE. . . .*

3 *After reviewing the data in consultation with the FDA, Biogen*  
4 *believes that the difference between the results of the new analysis of*  
5 *the larger dataset and the outcome predicted by the futility analysis*  
6 *was largely due to patients' greater exposure to high dose*  
7 *aducanumab. Multiple factors contributed to the greater exposure to*  
8 *aducanumab in the new analysis of the larger dataset, including data*  
9 *on a greater number of patients, a longer average duration of*  
10 *exposure to high dose, the timing of protocol amendments that*  
11 *allowed a greater proportion of patients to receive high dose, and the*  
12 *timing and pre-specified criteria of the futility analysis.*

13 \* \* \*

14 EMERGE and ENGAGE were Phase 3 multicenter, randomized,  
15 double-blind, placebo-controlled, parallel-group studies designed to  
16 evaluate the efficacy and safety of aducanumab. The primary objective  
17 of the studies was to evaluate the efficacy of monthly doses of  
18 aducanumab as compared with placebo in reducing cognitive and  
19 functional impairment as measured by changes in the CDR-SB score.  
20 Secondary objectives were to assess the effect of monthly doses of  
21 aducanumab as compared to placebo on clinical decline as measured by  
22 MMSE, ADAS-Cog 13, and ADCS-ADL-MCI.

23 (Emphasis added.)

24  
25  
26  
27  
28  
18. Also on October 22, 2019, Biogen released a slideshow entitled  
29 “Aducanumab Update” which provided the following slides regarding aducanumab:



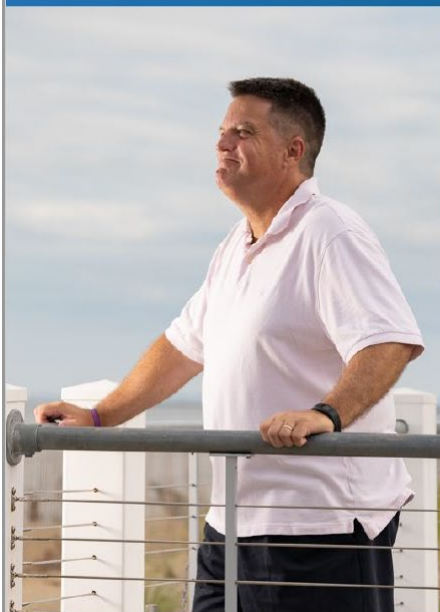
## Aducanumab summary

- 1 Following discussions with the FDA, Biogen plans to submit a regulatory filing in early 2020
- 2 The futility analysis in March 2019 was based on a smaller, earlier dataset with less exposure to high dose aducanumab. The result of the futility analysis was incorrect.
- 3 New analysis of larger dataset showed that aducanumab reduced clinical decline in patients with early Alzheimer's disease as measured by the pre-specified primary and secondary endpoints
- 4 The positive results of this new analysis were driven primarily by greater exposure to high dose aducanumab in the larger dataset
- 5 If approved, aducanumab would become the first therapy to reduce clinical decline in Alzheimer's disease



3

## Phase 3 aducanumab data



### Sufficient exposure to high dose aducanumab reduced clinical decline across multiple clinical endpoints

- This reduction in clinical decline was **statistically significant in EMERGE**
- Biogen believes data from patients who achieved **sufficient exposure to high dose aducanumab in ENGAGE support the findings of EMERGE**
- After consultation with the FDA, we believe that the **totality of these data support a regulatory filing**
- Patients included in the **futility analysis** had enrolled early in the studies and **had lower average exposure to aducanumab**
- **Two protocol amendments** were put in place to enable **more patients to reach high dose** and for a longer duration
- Differences between EMERGE and ENGAGE can mostly be accounted for by **greater exposure to high dose in EMERGE**

5

## Safety

- The safety and tolerability profile of aducanumab in EMERGE and ENGAGE was consistent with previous studies of aducanumab
- The most common adverse events were Amyloid-Related Imaging Abnormalities-Edema (ARIA-E, 35%) followed by headache (20%)
- The majority of patients who experienced ARIA-E (74%) did not experience symptoms during the ARIA-E episode
- ARIA-E episodes generally resolved within 4-16 weeks, typically without long-term clinical sequelae



16

19. Also on October 22, 2019, Biogen filed with the SEC its quarterly report on Form 10-Q for the period ended September 30, 2019 (the “3Q19 Report”) which was signed by Defendant Capello. Attached to the 3Q19 Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) signed by Defendants Vounatsos and Capello attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company’s internal control over financial reporting and the disclosure of all fraud.

20. The 3Q19 Report stated that following, in pertinent part, regarding aducanumab:

*Aducanumab (AB mAb)*

***On October 22, 2019, we and Eisai Co., Ltd. (Eisai) announced that we plan to pursue regulatory approval for aducanumab in the U.S. and that the Phase 3 EMERGE study met its primary endpoint***

– 10 –

1 *showing a significant reduction in clinical decline.* We believe that  
2 results from a subset of patients in the Phase 3 ENGAGE study who  
3 received sufficient exposure to high dose aducanumab support the  
4 findings from EMERGE. *The decision to file is based on a new*  
5 *analysis, conducted by Biogen in close consultation with the FDA, of*  
6 *a larger dataset from the Phase 3 EMERGE and ENGAGE trials that*  
7 *were discontinued in March 2019 following a futility analysis.*

8 (Emphasis added.)

9 21. On January 30, 2020, Biogen issued a press release entitled “BIOGEN  
10 REPORTS FULL YEAR 2019 REVENUES OF \$14.4 BILLION” which quoted  
11 Defendant Vounatsos touting aducanumab and its prospects with the FDA: “In  
12 addition, as part of our expanded pipeline, *we are excited about the prospects for*  
13 *aducanumab in Alzheimer’s disease and look forward to completing a regulatory*  
14 *filing in the U.S. as soon as possible.*” (Emphasis added.)

15 22. On February 2, 2020, Biogen filed with the SEC its annual report on  
16 Form 10-K for the period ended December 31, 2019 (the “2019 Annual Report”)  
17 which was signed by Defendant Vounatsos. Attached to the 2019 Annual Report  
18 were certifications pursuant to SOX signed by Defendants Vounatsos and Capello  
19 attesting to the accuracy of financial reporting, the disclosure of any material  
20 changes to the Company’s internal control over financial reporting and the  
21 disclosure of all fraud.

22 23. The Annual Report 2019 stated the following, in pertinent part,  
23 regarding aducanumab – including as one of the Company’s “Core Growth Areas”:  
24  
25  
26  
27  
28

Core  
Growth  
Areas

MS and Neuroimmunology	Opicinumab (anti-LINGO) - MS	Phase 2
	BIIB061 (oral remyelination) - MS	Phase 1
	BIIB091 (BTK inhibitor) - MS	Phase 1
Alzheimer's Disease and Dementia	Aducanumab (A $\beta$ mAb)* - Alzheimer's	Phase 3
	BAN2401 (A $\beta$ mAb)* - Alzheimer's	Phase 3
	BIIB092 (gosuranemab) - Alzheimer's	Phase 2
	BIIB076 (anti-tau mAb) - Alzheimer's	Phase 1
	BIIB080 (tau ASO) - Alzheimer's	Phase 1
Neuromuscular Disorders, including SMA and ALS	BIIB067 (tofersen) - ALS	Phase 3
	BIIB078 (IONIS-C9Rx)# - ALS	Phase 1
	BIIB110 (ActRIIA/B ligand trap) - SMA	Phase 1
	BIIB100 (XP01 inhibitor) - ALS	Phase 1
Movement Disorders, including Parkinson's Disease	BIIB054 (cinpanemab) - Parkinson's	Phase 2
	BIIB094 (ION859)# - Parkinson's	Phase 1
Ophthalmology	BIIB111 (timrepigene emparvovec) - CHM	Phase 3
	BIIB112 (RPGR gene therapy) - XLRP	Phase 2/3

\* \* \*

### *Aducanumab*

*In October 2019 we and our collaboration partner Eisai announced that we plan to pursue regulatory approval for aducanumab in the U.S. and that the Phase 3 EMERGE study met its primary endpoint showing a significant reduction in clinical decline.* We believe that results from a subset of patients in the Phase 3 ENGAGE study who received sufficient exposure to high dose aducanumab support findings from EMERGE. The decision to file is based on a new analysis, conducted in consultation with the FDA, of a larger dataset from the

1 Phase 3 EMERGE and ENGAGE trials that were discontinued in  
2 March 2019 following a futility analysis.

3 \* \* \*

4 *In 2020 we expect selling, general and administrative costs, including*  
5 *increases in headcount and other commercial infrastructure, to*  
6 *significantly increase as we support pre-launch activities associated*  
7 *with the potential regulatory approval of aducanumab.*

8 \* \* \*

9  
10 In March 2019, based on a pre-specified futility analysis, we  
11 discontinued the global Phase 3 trials, EMERGE and ENGAGE,  
12 designed to evaluate the efficacy and safety of aducanumab in patients  
13 with early AD. *A new analysis of a larger dataset from these trials,*  
14 *conducted in consultation with the FDA, showed that the Phase 3*  
15 *EMERGE study met its pre-specified primary and secondary*  
16 *endpoints.* In October 2019 we and Eisai announced that we plan to  
17 pursue regulatory approval for aducanumab in the U.S.

18 24. On April 22, 2020, Biogen issued a press release entitled “BIOGEN  
19 REPORTS Q1 2020 REVENUES OF \$3.5 BILLION” which stated the following,  
20 in relevant part, regarding aducanumab:

21 *Biogen has open BLA and has started to submit modules, expects to*  
22 *complete the U.S. filing for aducanumab in third quarter*

23 *Biogen initiated re-dosing study for aducanumab and higher dose study*  
24 *for SPINRAZA*

25 \* \* \*

26 Mr. Vounatsos added, “We delivered strong financial results in the first  
27 quarter, and we continued to develop and expand our pipeline,  
28 *including making good progress toward the U.S. regulatory filing for*  
*aducanumab,* as well as bolstering our efforts in gene therapy through

1 a collaboration with Sangamo. The magnitude and uncertainty  
2 surrounding this pandemic clearly introduce unanticipated and  
3 potentially unquantifiable risks to our business and results over the  
4 near-term. That said, *we believe that compelling opportunities exist in  
the therapeutic areas we are pursuing.*”

5 \* \* \*

6  
7 **Aducanumab Update**

8 Biogen provided the following update regarding aducanumab, an anti-  
9 amyloid beta antibody candidate for the potential treatment of  
10 Alzheimer’s disease that Biogen is developing in collaboration with  
Eisai Co., Ltd.:

- 11 • Biogen has an open Biological License Application  
12 (BLA) with the U.S. Food and Drug Administration  
(FDA) and has started to submit modules of the filing.
- 13 • Biogen has participated in additional formal interactions  
14 with the FDA using mechanisms such as Type C  
15 meetings and is preparing for a pre-BLA meeting,  
currently scheduled for the summer of 2020.
- 16 • Following the pre-BLA meeting, Biogen expects to  
17 complete the U.S. filing in the third quarter of 2020.

18 \* \* \*

19 Regulatory interactions: *Biogen is continuing its frequent interactions*  
20 *with regulatory authorities including for aducanumab.*

21 \* \* \*

22  
23 In April 2020 Biogen delivered an encore presentation of the Phase 3  
24 topline results for aducanumab at the virtual AAT-AD/PD™ focus  
25 meeting. The data in this presentation were previously presented at the  
26 Clinical Trials on Alzheimer’s Disease (CTAD) annual congress in  
December 2019.

1 \* \* \*

2 In March 2020 the first patient was dosed in the aducanumab re-dosing  
3 study, EMBARK, in line with Biogen's commitment to offer  
4 aducanumab to eligible patients who were previously in aducanumab  
5 clinical studies. EMBARK is a global re-dosing clinical study designed  
6 to evaluate aducanumab in eligible Alzheimer's disease patients who  
7 were actively enrolled in aducanumab studies (PRIME, EVOLVE,  
8 EMERGE, and ENGAGE) in March 2019.

9 (Emphasis added.)

10 25. On October 21, 2020, Biogen filed with the SEC its quarterly report on  
11 Form 10-Q for the period ended September 30, 2020 (the "3Q20 Report") which was  
12 signed by Defendant McDonnell. Attached to the 3Q20 Report were certifications  
13 pursuant to SOX signed by Defendants Vounatsos and McDonnell attesting to the  
14 accuracy of financial reporting, the disclosure of any material changes to the  
15 Company's internal control over financial reporting and the disclosure of all fraud.

16 26. The 3Q20 Report stated the following, in pertinent part, regarding  
17 aducanumab:

18 *Aducanumab (AB mAb)*

19  
20 In July 2020 we completed the submission of a Biologics License  
21 Application (BLA) to the U.S. Food and Drug Administration (FDA)  
22 for the approval of aducanumab, an anti-amyloid beta antibody  
23 candidate for the potential treatment of Alzheimer's disease that we  
24 are developing in collaboration with Eisai Co., Ltd. (Eisai). ***The***  
25 ***completed submission followed ongoing collaboration with the FDA***  
26 ***and includes clinical data from the Phase 3 EMERGE and***  
27 ***ENGAGE studies as well as the Phase 1b PRIME study.*** In August  
28 2020 the FDA accepted the BLA and granted Priority Review with a  
Prescription Drug User Fee Act action date on March 7, 2021.

1 During the first quarter of 2020, we initiated the EMBARK global re-  
2 dosing clinical study, which is *designed to evaluate aducanumab in*  
3 *eligible Alzheimer's disease patients who were actively enrolled in*  
4 *aducanumab studies (PRIME, EVOLVE, EMERGE and ENGAGE)*  
5 *in March 2019.*

6 \* \* \*

7 In October 2019 we and Eisai announced that, based on a new  
8 analysis, conducted by Biogen in consultation with the FDA, of a  
9 larger dataset from the Phase 3 EMERGE and ENGAGE trials that  
10 were discontinued in March 2019, *we plan to pursue regulatory*  
11 *approval for aducanumab in the U.S. In July 2020 we completed the*  
12 *submission of a BLA to the FDA for the approval of aducanumab.*

13 \* \* \*

14 Provided various development, regulatory or commercial milestones  
15 are achieved, we anticipate that we may pay approximately \$4.0  
16 million of milestone payments for the remainder of 2020. We may  
17 also pay \$100.0 million if aducanumab is launched in the U.S. In July  
18 2020 we completed the submission of a BLA to the FDA for the  
19 approval of aducanumab. During the third quarter of 2020, we paid  
20 Neurimmune SubOne AG (Neurimmune) \$75.0 million upon the  
21 completed submission of the BLA for aducanumab with the FDA,  
22 which was recognized as a charge to noncontrolling interests for the  
23 nine months ended September 30, 2020. In addition, for the nine  
24 months ended September 30, 2020, we recognized net profit-sharing  
25 income of \$33.8 million to reflect Eisai's 45% share of the \$75.0  
26 million milestone expense.

27 (Emphasis added.)

28 27. The statements contained in ¶¶17-26 were materially false and/or  
misleading because they misrepresented and failed to disclose the following adverse  
facts pertaining to the Company's business, operations and prospects, which were



1 known to Defendants or recklessly disregarded by them. Specifically, Defendants  
2 made false and/or misleading statements and/or failed to disclose that: (1) the larger  
3 dataset did not provide necessary data regarding aducanumab’s effectiveness; (2) the  
4 EMERGE study did not and would not provide necessary data regarding  
5 aducanumab’s effectiveness; (3) the PRIME study did not and would not provide  
6 necessary data regarding aducanumab’s effectiveness; (4) the data provided by the  
7 Company to the FDA’s Peripheral and Central Nervous System Drugs Advisory  
8 Committee did not support finding efficacy of aducanumab; and (5) as a result,  
9 Defendants’ statements about its business, operations, and prospects, were  
10 materially false and misleading and/or lacked a reasonable basis at all relevant times.  
11

12 **The Truth Emerges**

13 28. On November 6, 2020, *Reuters* published an article entitled “FDA  
14 advisory panel convenes to discuss whether Biogen Alzheimer's drug should be  
15 approved” which stated that “Biogen shares were halted ahead of the advisory panel  
16 meeting.”

17 29. Later on November 6, 2020, *Reuters* published an article entitled “U.S.  
18 FDA panel votes cannot ignore unsuccessful trial data on Biogen Alzheimer's drug”  
19 which stated the following, in pertinent part, regarding the FDA panel’s votes:

20 Most outside advisers to the U.S. Food and Drug Administration voted  
21 “no” to whether a successful trial of Biogen Inc’s BIIB.O experimental  
22 Alzheimer's drug can be viewed as evidence that it is effective without  
23 regard for a second, failed study.

24 They also voted that an earlier-stage study does not offer supportive  
25 evidence of Biogen's application for the drug, aducanumab. That vote  
26 was 7-0 with 4 “uncertain” votes.

1           30. Also on November 6, 2020, Biogen issued a press release entitled  
2 “UPDATE ON FDA ADVISORY COMMITTEE’S MEETING ON  
3 ADUCANUMAB IN ALZHEIMER’S DISEASE” which stated the following, in  
4 pertinent part, regarding the FDA vote:

5           Today, the U.S. Food and Drug Administration (FDA) Peripheral and  
6 Central Nervous System Drugs Advisory Committee voted 1 yes, 8 no  
7 and 2 uncertain on the question, “Does Study 302 (EMERGE), viewed  
8 independently and without regard for Study 301 (ENGAGE), provide  
9 strong evidence that supports the effectiveness of aducanumab for the  
10 treatment of Alzheimer’s disease?”. The Advisory Committee also  
11 voted 0 yes, 7 no and 4 uncertain on the question, “Does Study 103  
12 (PRIME) provide supportive evidence of the effectiveness of  
13 aducanumab for the treatment of Alzheimer’s disease?”, and 5 yes, 0  
14 no and 6 uncertain on the question, “Has the Applicant presented strong  
15 evidence of a pharmacodynamic effect of aducanumab on Alzheimer’s  
16 disease pathophysiology?”. Finally, the Advisory Committee voted 0  
17 yes, 10 no and 1 uncertain on the question, “In light of the  
18 understanding provided by the exploratory analyses of Study 301 and  
19 Study 302, along with the results of Study 103 and evidence of a  
20 pharmacodynamic effect on Alzheimer’s disease pathophysiology, it is  
21 reasonable to consider Study 302 as primary evidence of effectiveness  
22 of aducanumab for the treatment of Alzheimer’s disease?”

23           31. On this news, Biogen’s stock price fell \$92.64 per share, or 28%, to  
24 close at \$236.26 per share on November 9, 2020, the next trading day, damaging  
25 investors.

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

**PLAINTIFF’S CLASS ACTION ALLEGATIONS**

33. 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



- 1 (a) whether Defendants' acts as alleged violated the federal securities  
2 laws;
- 3 (b) whether Defendants' statements to the investing public during the  
4 Class Period misrepresented material facts about the financial  
5 condition, business, operations, and management of the Company;
- 6 (c) whether Defendants' statements to the investing public during the  
7 Class Period omitted material facts necessary to make the statements  
8 made, in light of the circumstances under which they were made, not  
9 misleading;
- 10 (d) whether the Individual Defendants caused the Company to issue false  
11 and misleading SEC filings and public statements during the Class  
12 Period;
- 13 (e) whether Defendants acted knowingly or recklessly in issuing false and  
14 misleading SEC filings and public statements during the Class Period;
- 15 (f) whether the prices of the Company's securities during the Class Period  
16 were artificially inflated because of the Defendants' conduct  
17 complained of herein; and
- 18 (g) whether the members of the Class have sustained damages and, if so,  
19 what is the proper measure of damages.  
20

21 38. A class action is superior to all other available methods for the fair and  
22 efficient adjudication of this controversy since joinder of all members is  
23 impracticable. Furthermore, as the damages suffered by individual Class members  
24 may be relatively small, the expense and burden of individual litigation make it  
25 impossible for members of the Class to individually redress the wrongs done to  
26 them. There will be no difficulty in the management of this action as a class action.  
27



1 Defendants omitted material information in their Class Period statements in  
2 violation of a duty to disclose such information, as detailed above.

3 **COUNT I**

4 **Violation of Section 10(b) of The Exchange Act and Rule 10b-5**

5 **Against All Defendants**

6 42. Plaintiff repeats and realleges each and every allegation contained  
7 above as if fully set forth herein.

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

11 44. During the Class Period, the Company and the Individual Defendants,  
12 individually and in concert, directly or indirectly, disseminated or approved the  
13 false statements specified above, which they knew or deliberately disregarded were  
14 misleading in that they contained misrepresentations and failed to disclose material  
15 facts necessary in order to make the statements made, in light of the circumstances  
16 under which they were made, not misleading.

17 45. The Company and the Individual Defendants violated §10(b) of the  
18 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to  
19 defraud; made untrue statements of material facts or omitted to state material facts  
20 necessary in order to make the statements made, in light of the circumstances under  
21 which they were made, not misleading; and/or engaged in acts, practices and a  
22 course of business that operated as a fraud or deceit upon plaintiff and others  
23 similarly situated in connection with their purchases of the Company's securities  
24 during the Class Period.  
25  
26  
27  
28



1 result of the Company's and the Individual Defendants' false and misleading  
2 statements.

3 49. Had Plaintiff and the other members of the Class been aware that the  
4 market price of the Company's securities had been artificially and falsely inflated  
5 by the Company's and the Individual Defendants' misleading statements and by the  
6 material adverse information which the Company's and the Individual Defendants  
7 did not disclose, they would not have purchased the Company's securities at the  
8 artificially inflated prices that they did, or at all.

9 50. As a result of the wrongful conduct alleged herein, Plaintiff and other  
10 members of the Class have suffered damages in an amount to be established at trial.

11 51. By reason of the foregoing, the Company and the Individual  
12 Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5  
13 promulgated thereunder and are liable to the Plaintiff and the other members of the  
14 Class for substantial damages which they suffered in connection with their  
15 purchases of the Company's securities during the Class Period.  
16

17 **COUNT II**

18 **Violation of Section 20(a) of The Exchange Act**

19 **Against The Individual Defendants**

20 52. Plaintiff repeats and realleges each and every allegation contained in  
21 the foregoing paragraphs as if fully set forth herein.

22 53. During the Class Period, the Individual Defendants participated in the  
23 operation and management of the Company, and conducted and participated,  
24 directly and indirectly, in the conduct of the Company's business affairs. Because  
25 of their senior positions, they knew the adverse non-public information regarding  
26 the Company's business practices.  
27





