UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

LEONARD SHAPIRO, Individually and on behalf of all others similarly situated, Plaintiff, v. BIOGEN INC., MICHEL VOUNATSOS, JEFFREY D. CAPELLO, MICHAEL R. MCDONNELL, ALFRED W. SANDROCK JR., and SAMANTHA BUDD HAEBERLEIN, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS JURY TRIAL DEMANDED

Plaintiff Leonard Shapiro ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his undersigned counsel, hereby brings this Class Action Complaint for Violation of Federal Securities Law ("Complaint") against Biogen Inc. ("Company" or "Biogen"); Michel Vounatsos ("Vounatsos"), Biogen's current Chief Executive Officer ("CEO") and Director; Jeffrey D. Capello ("Capello"), Biogen's former Chief Financial Officer ("CFO") and Executive Vice President; Michael R. McDonnell ("McDonnell"), Biogen's present CFO and Vice President; Alfred W. Sandrock Jr. ("Sandrock"), Biogen's Executive Vice President and Chief Medical Officer since 2015; and Samantha Budd Haeberlein ("Haeberlein"), Biogen's Vice President of Alzheimer's Disease Discovery & Development, based upon, *inter alia*, the investigation conducted by and under the supervision of Plaintiff's counsel, which included a review of the Company's public documents, conference calls, and announcements, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding the Company, analysts' reports and advisories about the Company and readily obtainable information. Plaintiff's counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to, or are exclusively within the custody or control of, the Company and Defendants Vounatsos, Capello, McDonnell, Sandrock, and Haeberlein. 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 lawsuit on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired common shares of Biogen stock between October 22, 2019 and November 6, 2020, both dates inclusive (the "Class Period"), seeking to recover damages by Defendants' violation 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 Delaware Company headquartered in Cambridge, Massachusetts. Biogen develops, discovers, and manufactures therapies for the treatment of neurological and neurodegenerative diseases, as well as autoimmune and hematologic disorders. One of the Company's principal products in development is aducanumab, which is an investigational drug studied for the treatment of Alzheimer's disease – an irreversible and progressive degenerative disorder and the leading cause of dementia.

3. In 2015, with the aim of establishing aducanumab as an effective treatment for Alzheimer's disease, Biogen launched two identical phase 3 trials, which compared the effects of 2 dosing regimens of aducanumab versus placebo. At the time when approximately 50% of the participants completed 78 weeks of treatment, Biogen conducted a futility analysis to assess the ability of the ongoing clinical trials to achieve their objective. Based on the results of Biogen's futility analysis, Biogen determined the trials were unlikely to meet their primary efficacy. Accordingly, in March 2019, Biogen announced the termination of its clinical trials.

4. Despite the disappointing results of the futility analysis, Biogen was not ready to part with its vision of reaping enormous financial benefits stemming from the introduction of a breakthrough therapy for the treatment of Alzheimer's disease. Accordingly, in October 2019 — approximately seven months after Biogen discontinued its phase 3 trials — Biogen shocked the medical community by announcing that its previously terminated trials were going to be revived based on newly analyzed data sets. Following the resurrection of aducanumab's development program, Biogen embarked on months-long campaign to convince the investing public, as well as

the scientific community, including the FDA, that the post hoc data supported the conclusion that aducanumab was an effective solution in treating Alzheimer's disease.

5. Since the October 2019 announcement, Biogen executives disseminated dozens of false and misleading statements in which they touted the post hoc data analyses purportedly arising from its phase 3 and phase 1 clinical trials and the implications thereof on aducanumab's regulatory approval. For example, the Individual Defendants promoted the phase 3 clinical trials as providing consistent data for the support of aducanumab's efficacy while the phase 1 trials presented further support for aducanumab's regulatory approval. To give credence to their courageous claims about aducanumab's prospects of obtaining regulatory approval, Biogen painted a picture of having the support of the FDA, who purportedly was exercising an intense oversight over Biogen's post hoc data analyses and research. Based on Defendants' misleading claims regarding the strength and validity of its data analyses, the investing public reasonably expected that Biogen would secure regulatory approval of aducanumab during an upcoming review by the FDA Advisory Panel.

6. In reality, however — and unbeknownst to the investing public — Biogen's post hoc analyses were an effort to explain away the discordant phase 3 trial results. To achieve that objective, Biogen relied on dubious statistical gymnastics and scientifically and statistically unsound practices, which could not — and did not — withstand scrutiny by the scientific and medical community. Contrary to Biogen's bold representations, the totality of the data did not provide sufficient evidence to support the efficacy of aducanumab for the treatment of Alzheimer's disease.

7. The investing public learned the truth on November 6, 2020, when the FDA's independent Advisory Panel reviewed Biogen's submission. After a seven-hour virtual meeting, the FDA Advisory Panel voted nearly unanimously that it was not "reasonable" to consider

Biogen's research as primary evidence of effectiveness of aducanumab. In an overwhelmingly negative committee meeting, the Advisory Panel delivered harsh words of reality for Biogen, observing that its data was "strikingly incongruent" and lacked "compelling statistical review." After the Advisory Panel's vote, chances aducanumab's regulatory approval significantly diminished, leaving investors shocked and disappointed.

8. On this news, the price of Biogen common shares dropped $92.64 per share, or 28%, to close at $236.26 per share, wiping more than $14 billion in investor wealth.

9. Throughout the Class Period, Defendants made materially false and misleading statements, and failed to disclose material adverse facts about the Company's business, operational, and compliance policies. Specifically, Defendants made false and/or misleading statements and failed to disclose to investors that: (1) Study 302, viewed independently, did not provide strong evidence that supported the effectiveness of aducanumab; (2) Study 103 did not provide supportive evidence of the effectiveness of aducanumab; (3) Study 302 could not be considered as primary evidence of effectiveness of aducanumab for the treatment of Alzheimer's disease in light of the results of the exploratory analyses of Study 301 and 302 and the results of Study 103; (4) the totality of the data did not provide sufficient evidence to support efficacy of aducanumab for the treatment of Alzheimer's disease; and (5) as a result, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

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

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