UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

DAVID DEPUTY, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AKEBIA THERAPEUTICS, INC., JOHN P. BUTLER, DAVID A. SPELLMAN, and JASON A. AMELLO, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff David Deputy ("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 the 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 Akebia Therapeutics, Inc. ("Akebia" 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 Akebia securities between

June 28, 2018 and September 2, 2020, 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. Akebia is a biopharmaceutical company that focuses on the development and commercialization of renal therapeutics for patients with kidney diseases. The Company's lead investigational product candidate is vadadustat, an oral therapy, which is in Phase 3 development for the treatment of anemia due to chronic kidney disease ("CKD") in dialysis-dependent and non-dialysis dependent ("NDD") adult patients.

3. Akebia's Phase 3 clinical programs for vadadustat include, among others, the PRO$_2$TECT program in NDD-CKD patients with anemia (the "PRO$_2$TECT Program"). The PRO$_2$TECT Program's primary safety endpoint was defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of major adverse cardiovascular events ("MACE").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) vadadustat was not as safe in treating NDD-CKD patients with anemia as Defendants had represented; (ii) as a result, Defendants overstated the PRO$_2$TECT Program's clinical prospects; (iii) accordingly, Defendants also overstated vadadustat's overall commercial and regulatory prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On September 3, 2020, Akebia issued a press release announcing "top-line results" from the PRO$_2$TECT Program, disclosing that "[v]adadustat did not meet the primary safety

endpoint of the PRO2TECT program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of [MACE.]"

6. On this news, Akebia's common stock price fell $7.35 per share, or 73.5%, to close at $2.65 per share on September 3, 2020.

7. 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

8. 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).

9. 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.

10. 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), as the alleged misstatements entered and subsequent damages took place in this Judicial District. Pursuant to Akebia's most recent annual report on Form 10-K, as of February 23, 2022, there were 181,231,071 shares of the Company's common stock outstanding. Akebia's common stock trades on the Nasdaq Global Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in Akebia common stock located in the U.S., some of whom undoubtedly reside in this Judicial District.

11. 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

12. Plaintiff, as set forth in the attached Certification, acquired Akebia securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Akebia is a Delaware corporation with principal executive offices located at 245 First Street, Cambridge, Massachusetts 02142. The Company's common stock trades in an efficient market on the NASDAQ under trading symbol "AKBA".

14. Defendant John P. Butler ("Butler") has served as Akebia's President, Chief Executive Officer, and a Director of the Company at all relevant times.

15. Defendant David A. Spellman ("Spellman") has served as Akebia's Senior Vice President ("SVP"), Chief Financial Officer ("CFO"), and Treasurer since June 29, 2020.

16. Defendant Jason A. Amello ("Amello") served as Akebia's SVP, CFO, and Treasurer from before the start of the Class Period to June 29, 2020.

17. Defendants Butler, Spellman, and Amello are sometimes referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Akebia's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Akebia'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 Akebia, 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.

19. Akebia and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

20. Akebia is a biopharmaceutical company that focuses on the development and commercialization of renal therapeutics for patients with kidney diseases. The Company's lead investigational product candidate is vadadustat, an oral therapy, which is in Phase 3 development for the treatment of anemia due to CKD in, *inter alia*, NDD adult patients.

21. Akebia's Phase 3 clinical programs for vadadustat include, among others, the PRO$_2$TECT Program in NDD-CKD patients with anemia. The PRO$_2$TECT Program's primary safety endpoint was defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of MACE.

22. Akebia has a collaboration agreement with, among others, Mitsubishi Tanabe Pharma Corporation ("MTPC") for the development and commercialization of vadadustat in Japan and other Asian countries. Throughout the Class Period, the Company touted the safety results of a contemporaneous Phase 3 program conducted by MTPC in Japan, which assessed vadadustat in NDD-CKD patients with anemia, while asserting its purported positive implications for the PRO$_2$TECT Program.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on June 28, 2018, when Akebia issued a press release regarding its anticipated merger with Keryx Biopharmaceuticals, Inc. ("Keryx"). That press release highlighted the purported "Large Market Opportunity" of the combined company, describing vadadustat as "designed to mimic the physiologic effect of altitude on oxygen availability" to "improve oxygen delivery" with "the potential to become a new standard of care for patients with anemia due to CKD who currently rely on injectable ESAs [erythropoietin-stimulating agents], a multi-billion-dollar market."

24. The same June 28, 2018 press release also asserted that Akebia's merger with Keryx "Creates Potential for Accelerated Growth and Organizational Synergies[,]" including "driving launch momentum for vadadustat in the" U.S., and "driv[ing] the launch preparation and execution for vadadustat in the" U.S.

25. On August 8, 2018, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2018 (the "2Q18 10-Q"). That filing stated, in relevant part:

> Vadadustat is designed to stimulate erythropoiesis and effectively treat renal anemia while avoiding the supra-physiologic EPO [erythropoietin] levels previously observed with injectable ESAs. In addition, vadadustat, if approved, would provide patients with an oral treatment option, rather than an injection. For these reasons, we believe that vadadustat has the potential to set a new standard of care for the treatment of anemia due to CKD.
>
> Phase 1 and Phase 2 data led us to the design of our Phase 3 clinical program for vadadustat.

26. Appended as an exhibit to the 2Q18 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Butler and Amello certified that "[t]he [2Q18 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the" Exchange Act,

and that "[t]he information contained in the [2Q18 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

27. On November 8, 2018, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2018 (the "3Q18 10-Q"). That filing contained the same statements as referenced in ¶ 25, *supra*, regarding vadadustat's purported potential to "set a new standard of care" in treating patients suffering from anemia due to CKD, and the prior clinical data supporting the PRO$_2$TECT Program.

28. Appended as an exhibit to the 3Q18 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

29. On March 12, 2019, Akebia issued a press release announcing top-line results from MTPC's pivotal Phase 3 study in, among others, NDD-CKD subjects, indicating that vadadustat was safer than darbepoetin alfa in treating NDD-CKD patients with anemia at 24 weeks, while downplaying safety risks observed. Specifically, that press release stated, in relevant part:

> The . . . study assessed the efficacy and safety of vadadustat compared to darbepoetin alfa, an erythropoiesis stimulating agent (ESA), in 304 Japanese [NDD] subjects with anemia due to CKD, with a treatment duration of 52 weeks. Data from the planned analysis at 24 weeks are provided . . . . The incidence of adverse events (AEs) was 72.2% in the vadadustat-treated group compared to 73.2% in the darbepoetin alfa-treated group. The most common AEs reported in vadadustat-treated subjects were nasopharyngitis (14.6%), diarrhea (10.6%), constipation (5.3%), and contusion (5.3%). The incidence of serious adverse events (SAEs) was 13.9% in the vadadustat-treated group compared to 14.4% in the darbepoetin alfa-treated group; no SAE was considered related to study drug. No deaths were reported in the vadadustat-treated group, and one fatal myocardial infarction was reported in the darbepoetin alfa-treated group, which was assessed as not related to study drug.

30. The same March 12, 2019 press release also quoted Defendant Butler, who stated, in relevant part, that "[c]ollectively, these data provide further confirmation of vadadustat's

potential to meaningfully transform the treatment paradigm for patients with anemia due to CKD[.]"

31. On March 26, 2019, Akebia 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, 2018 (the "2018 10-K"). In addition to reiterating vadadustat's potential to "to set a new standard of care for the treatment of anemia due to CKD[,]" that filing contained substantively the same statements as referenced in ¶ 29, *supra*, regarding MTPC's Phase 3 clinical program results for vadadustat, which indicated that vadadustat was safer than darbepoetin alfa in treating NDD-CKD patients with anemia.

32. The 2018 10-K also reiterated that "Phase 1 and Phase 2 data led us to the design of our Phase 3 clinical program for vadadustat[,]" while noting that Akebia "ha[d] completed twenty-two Phase 1 and Phase 2 studies of vadadustat" that "included [*inter alia*] . . . NDD-CKD . . . patients, and support continued development of vadadustat."

33. Appended as an exhibit to the 2018 10-K were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

34. On May 9, 2019, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2019 (the "1Q19 10-Q"). That filing asserted, in relevant part, that "vadadustat has the potential to set a new standard of care in the treatment of anemia due to CKD, acting via a novel hypoxia inducible factor . . . pathway[,]" which "is the primary regulator of the production of red blood cells . . . in the body, as well as other important metabolic functions."

35. Appended as an exhibit to the 1Q19 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

36. On July 23, 2019, Akebia issued a press release announcing MTPC's submission of a Japanese New Drug Application to the Ministry of Health, Labor and Welfare in Japan for manufacturing and marketing approval of vadadustat as a treatment for anemia due to CKD, noting that "[t]his submission is supported by positive top-line data from MTPC's two Phase 3, active-controlled, pivotal studies evaluating the [*inter alia*] . . . safety of vadadustat in Japanese subjects with anemia due to CKD[.]"

37. On August 8, 2019, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2019 (the "2Q19 10-Q"). That filing contained substantively the same statements as referenced in ¶ 25, *supra*, regarding vadadustat's purported potential to "set a new standard of care" in treating patients suffering from anemia due to CKD.

38. Appended as an exhibit to the 2Q19 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

39. On September 3, 2019, Akebia issued a press release announcing, *inter alia*, full enrollment in the Phase 3 studies comprising the PRO$_2$TECT Program. That press release quoted Defendant Butler, who stated, in relevant part:

> We have tremendous confidence in the global Phase 3 program that we've designed for vadadustat and believe we are well positioned for clinical, regulatory and commercial success. Importantly, our program includes multiple secondary efficacy and safety endpoints to assess both clinically and commercially important areas of differentiation between vadadustat and the current standard of care, ESAs . . . . We believe these data will be extremely relevant for physicians, patients and payers as they make important care decisions.

40. On November 9, 2019, Akebia issued a press release announcing, among other results, positive 52-week safety data for vadadustat from two phase 3 studies conducted by MTPC in NDD-CKD subjects, again indicating that vadadustat was safer than darbepoetin alfa in treating

NDD-CKD patients with anemia, while downplaying safety risks observed. Specifically, that press release stated, in relevant part:

> MTPC's phase 3 randomized, open-label, active-controlled correction and conversion study assessed the . . . safety of vadadustat compared to darbepoetin alfa, an erythropoiesis stimulating agent (ESA), in 304 Japanese [NDD] subjects with anemia due to CKD, with a treatment duration of 52 weeks . . . . The incidence of adverse events (AEs) was 90.1% in the vadadustat-treated group compared to 92.2% in the darbepoetin alfa-treated group. The top three most common AEs reported in vadadustat-treated subjects were nasopharyngitis (24.5%), diarrhea (11.9%), and constipation (9.3%). The incidence of serious adverse events (SAEs) was 27.8% in the vadadustat-treated group compared to 32.0% in the darbepoetin alfa-treated group; no SAE was considered related to study drug. No deaths were reported in the vadadustat-treated group.

41. The same November 9, 2019 press release also quoted Defendant Butler, who stated, in relevant part, that "[t]he 52-week data from MTPC's studies reinforce our belief in vadadustat's potential to make a difference in the lives of people impacted by anemia due to CKD."

42. On November 12, 2019, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2019 (the "3Q19 10-Q"). That filing contained substantively the same statements as referenced in ¶ 25, *supra*, regarding vadadustat's purported potential to "set a new standard of care" in treating patients suffering from anemia due to CKD.

43. Appended as an exhibit to the 3Q19 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

44. On March 12, 2020, Akebia 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, 2019 (the "2019 10-K"). That filing noted that "[a]s a result of the safety concerns associated with ESAs, today, a high proportion of NDD-CKD patients with anemia are either not treated or inadequately treated despite having low hemoglobin levels[,]" while asserting that "[i]n contrast

to treatment with ESAs, we believe vadadustat . . . has the potential to expand the number of NDD-CKD patients receiving treatment by offering an alternative oral treatment for anemia due to CKD with a differentiated safety profile."

45. Specifically, the 2019 10-K represented that, based on "key clinical findings" and "other data[,]" Akebia "believe[s] vadadustat has the potential to be a treatment for anemia due to CKD with a differentiated safety profile compared with the current standard of care, injectable ESAs, by . . . stimulating erythropoiesis and avoiding supraphysiologic EPO levels[,]" "increasing hemoglobin in a predictable and controlled manner[,]" and "minimizing hemoglobin excursions and cycling."

46. Additionally, the 2019 10-K reiterated the results from MTPC's phase 3 studies, referenced in in ¶ 40, *supra*, indicating that vadadustat was safer than darbepoetin alfa in treating NDD-CKD patients with anemia, while downplaying safety risks observed.

47. Appended as an exhibit to the 2019 10-K were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

48. On May 5, 2020, Akebia held a conference call with investors and analysts to discuss the Company's first quarter 2020 financial and operating results (the "1Q20 Investor Call"). On that call, Defendant Butler highlighted Defendants' confidence in the PRO$_2$TECT Program's clinical prospects, stating, in relevant part:

> [W]e have significantly advanced PRO$_2$TECT, our global Phase 3 study evaluating the safety and efficacy of vadadustat in [NDD] adult patients with anemia due to CKD. We've achieved the target number of MACE events for the study and expect top line data mid-year as planned . . . .
>
> We can't wait to get these data in front of the FDA and other regulatory agencies as soon as possible. Upon successful completion of our Phase 3 program, and with PRO$_2$TECT data in hand, we plan to submit the regulatory filings for marketing approval of vadadustat for both dialysis dependent and non-dialysis adult patients in the U.S. as quickly as possible.

49. Also on May 5, 2020, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the "1Q20 10-Q"). In addition to reiterating vadadustat's potential to "set a new standard of care" in treating patients suffering from anemia due to CKD, that filing stated that "[w]e plan to file for regulatory approval in the [U.S.] and other regions upon successful completion of the global Phase 3 studies for vadadustat, which includes the PRO$_2$TECT studies of vadadustat for the treatment of anemia due to CKD in NDD-CKD patients that we expect to read out in mid-2020[,]"again indicating to investors that Defendants were confident in the PRO$_2$TECT Program's clinical prospects.

50. Appended as an exhibit to the 1Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Butler and Amello.

51. On May 31, 2020, an article entitled "Akebia Therapeutics: A Clear Path To A Blockbuster CKD-Anemia Treatment" was published on *Seeking Alpha*, an online investor news service and content provider, exemplifying how Defendants had hyped the PRO$_2$TECT Program's clinical prospects to the market. Specifically, that article highlighted "Management's strong faith in PRO2TECT results[,]" stating, in relevant part, that "[t]he . . . phase 3 PRO2TECT trial was treated almost as if it were a done deal by Akebia management on the" the 1Q20 Investor Call, while explicitly citing Defendant Butler's statements referenced in ¶ 48, *supra*.

52. On June 29, 2020, Akebia issued a press release announcing that MTPC had obtained approval of vadadustat in Japan for treating anemia due to CKD in, among others, NDD-CKD adult patients. That press release stated, in relevant part, that "[t]he approval was based on data from the vadadustat development program, including MTPC's two Phase 3 active-controlled

pivotal studies, which support the . . . safety of vadadustat in treating . . . adult patients . . . not on dialysis with anemia due to CKD in Japan."

53. The same press release also quoted Defendant Butler, who stated that "[w]e believe this milestone marks the beginning of the next phase of Akebia's growth story[.]"

54. On August 10, 2020, Akebia filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "2Q20 10-Q"). That filing reiterated that Akebia "had significantly advanced PRO$_2$TECT, the second of our two global Phase 3 cardiovascular outcomes programs, and achieved the target number of major adverse cardiovascular events, or MACE, for the study."

55. Appended as an exhibit to the 2Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 26, *supra*, signed by Defendants Spellman and Amello.

56. The statements referenced in ¶¶ 23-50 and 52-55 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) vadadustat was not as safe in treating NDD-CKD patients with anemia as Defendants had represented; (ii) as a result, Defendants overstated the PRO$_2$TECT Program's clinical prospects; (iii) accordingly, Defendants also overstated vadadustat's overall commercial and regulatory prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

57. On September 3, 2020, during pre-market hours, Akebia issued a press release announcing "top-line results" from the PRO$_2$TECT Program. Although that press release noted

that vadadustat achieved the primary and key secondary efficacy endpoint in each of the two PRO$_2$TECT studies, the drug had failed to meet its primary safety endpoint. Specifically, that press release stated, in relevant part:

> ***Vadadustat did not meet the primary safety endpoint of the PRO$_2$TECT program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of [MACE***], which is the composite of all-cause mortality, non-fatal myocardial infarction, and non-fatal stroke across both PRO$_2$TECT studies.
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> * * *
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> The upper bound of the 95% confidence interval of the Hazard Ratio (HR) was above the pre-specified NI margin of 1.25 for primary MACE analysis (HR 1.17, 95% CI: 1.01, 1.36). MACE is defined as the composite endpoint of all-cause mortality, non-fatal myocardial infarction, and non-fatal stroke.
>
> The incidence of treatment emergent adverse events during the Correction study in the vadadustat-treated patients was 90.9%, and 91.6% in darbepoetin alfa-treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (34.7%/ 35.2%), hypertension (17.7%/ 22.1.%), hyperkalemia (12.3.%/ 15.6%), urinary tract infection (12.9%/ 12.0%), diarrhea (13.9%/ 10.0%), peripheral oedema (12.5%/ 10.5%), fall (9.6%/ 10%) and nausea (10%/ 8.2%). ***Serious treatment emergent adverse events were 65.3% for vadadustat-treated patients and 64.5% for darbepoetin alfa-treated patients. The incidence of treatment emergent adverse events during the Conversion study in vadadustat treated patients was 89.1% and 87.7% in darbepoetin alfa-treated patients.*** During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (27.5%/ 28.4%), hypertension (14.4%/ 14.8%), urinary tract infection (12.2%/ 14.5%), diarrhea (13.8.%/ 8.8.%), peripheral oedema (9.9%/ 10.1%) and pneumonia (10.0%/ 9.7%). ***Serious treatment emergent adverse events were 58.5% for vadadustat-treated patients and 56.6% for darbepoetin alfa-treated patients.***

(Emphases added.)

58. On this news, Akebia's common stock price fell $7.35 per share, or 73.5%, to close at $2.65 per share on September 3, 2020.

59. An article published on *Fierce Pharma* the next day, entitled "Akebia crashes on vadadustat flop in larger anemia indication. Will AZ, FibroGen own the market?", reflected just

how severely Akebia's September 3, 2020 press release had caught both investors and analysts off-guard with respect to the PRO$_2$TECT Program's clinical results, stating, in relevant part:

> On Thursday, Akebia said its Otsuka-partnered vadadustat was linked to increased heart risks compared with Amgen's standard erythropoietin therapy Aranesp in [NDD] patients with anemia due to [CKD].
>
> The primary safety flop in the phase 3 PRO2TECT trial shocked Akebia investors, who sent the company's stock southward by about 75% on Thursday. The failure was unexpected mainly because the drug already boasts an approval in Japan as Vafseo in broader kidney disease-related anemia, and its INNO2VATE dialysis data were positive on every front; the drug even matched up to Aranesp on time to first occurrence of major adverse cardiovascular events.
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> * * *
>
> Previously, pooled phase 3 analyses showed the risk of major CV side effects was comparable between roxadustat and placebo. But vadadustat has now shown it fared even worse than the already risky Aranesp in that department.
>
> "We think today's data have ended vada's opportunity in [NDD patients], at least from a commercial standpoint, although Akebia management continued to guide to an alternative path forward in this indication," Porges wrote in a Thursday note to client.
>
> According to Piper Sandler analyst Christopher Raymond, Akebia management is now looking at subgroup analyses as its potential regulatory next step, though he acknowledged the feeling of a "collective investor-eye-roll" when this proposal was put forward.
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> * * *
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> Despite vadadustat still having a "credible path forward" in dialysis anemia, shares behaved as if the drug was completely dead, Raymond noted. That may just be the case. To SVB Leerink's Porges, the nondialysis safety scare is likely to significantly limit the product's adoption in dialysis, too, since he figures roxadustat will win a broad and clean label.

60. 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.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

61. 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 Akebia 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.

62. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Akebia 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 Akebia 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.

63. 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.

64. 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.

65. 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 Akebia;
- whether the Individual Defendants caused Akebia 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 Akebia 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.

66. 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.

67. 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;
- Akebia 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 Akebia 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.

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

69. 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)

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

71. 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.

72. 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 Akebia securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Akebia 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.

73. 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 Akebia 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 Akebia's finances and business prospects.

74. By virtue of their positions at Akebia, 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.

75. 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 Akebia, the Individual Defendants had knowledge of the details of Akebia's internal affairs.

76. 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 Akebia. 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 Akebia'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 Akebia securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Akebia's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Akebia 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.

77. During the Class Period, Akebia 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 Akebia 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 Akebia securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Akebia securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

78. 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.

79. 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)

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

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

82. 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 Akebia's

financial condition and results of operations, and to correct promptly any public statements issued by Akebia which had become materially false or misleading.

83. 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 Akebia disseminated in the marketplace during the Class Period concerning Akebia's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Akebia to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Akebia 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 Akebia securities.

84. Each of the Individual Defendants, therefore, acted as a controlling person of Akebia. By reason of their senior management positions and/or being directors of Akebia, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Akebia to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Akebia 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.

85. 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 Akebia.

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: March 14, 2022