UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AXSOME THERAPEUTICS, INC., HERRIOT TABUTEAU, NICK PIZZIE, MARK JACOBSON, CEDRIC O'GORMAN, and KEVIN LALIBERTE, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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 Axsome Therapeutics, Inc. ("Axsome" 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 Axsome securities

between December 30, 2019 and April 22, 2022, 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. Axsome is a biopharmaceutical company that engages in the development of novel therapies for central nervous system ("CNS") disorders in the U.S. The Company is developing, among other product candidates, AXS-07, a novel, oral, rapidly absorbed, multi-mechanistic, and investigational medicine for the acute treatment of migraine.

3. Axsome consistently touted AXS-07's regulatory and commercial prospects in anticipation of the Company's submission a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for AXS-07 for the acute treatment of migraine (the "AXS-07 NDA") based on the drug's positive results in two Phase 3 trials. However, unbeknownst to investors, the Company's preparation and eventual submission of the AXS-07 NDA was plagued with chemistry, manufacturing, and control ("CMC") issues.

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) Axsome's CMC practices were deficient with respect to AXS-07 and its manufacturing process; (ii) as a result, Axsome was unlikely to submit the AXS-07 NDA on its initially represented timeline; (iii) the foregoing CMC issues remained unresolved at the time that the FDA reviewed the AXS-07 NDA; (iv) accordingly, the FDA was unlikely to approve the AXS-07 NDA; (v) as a result of all the foregoing, Axsome had overstated AXS-07's regulatory and commercial prospects; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On November 5, 2020, Axsome issued a press release reporting the Company's third quarter 2020 results. That press release disclosed that the Company "plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

6. On this news, Axsome's stock price fell $5.22 per share, or 6.99%, to close at $69.51 per share on November 5, 2020.

7. Then, on April 25, 2022, Axsome disclosed in an SEC filing that, "[o]n April 22, 2022, Axsome . . . was informed by the [FDA] that [CMC] issues identified during the FDA's review of the Company's [NDA] for its AXS-07 product candidate for the acute treatment of migraine are unresolved." That filing also disclosed that "[b]ased upon the time remaining in the NDA review cycle, the Company expects to receive a Complete Response Letter [('CRL')] with respect to this NDA on or about the Prescription Drug User Fee Act [('PDUFA')] target action date of April 30, 2022."

8. On this news, Axsome's stock price fell $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022.

9. Finally, on May 2, 2022, Axsome announced that it received a CRL from the FDA regarding the AXS-07 NDA for the acute treatment of migraine. According to the Company, "[t]he principal reasons given in the CRL relate to [CMC] considerations" including "the need for additional CMC data pertaining to the drug product and manufacturing process."

10. 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

11. 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).

12. 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.

13. 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). Axsome is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

14. 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

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

16. Defendant Axsome is a Delaware corporation with principal executive offices located at 22 Cortlandt Street, 16th Floor, New York, New York 10007. Axsome's common stock trades in an efficient market on the NASDAQ under the trading symbol "AXSM".

17. Defendant Herriot Tabuteau, M.D. ("Tabuteau") has served as Axsome's Founder, Chief Executive Officer, and Chairman of the Board of Directors at all relevant times.

18. Defendant Nick Pizzie ("Pizzie") has served as Axsome's Chief Financial Officer at all relevant times.

19. Defendant Mark Jacobson ("Jacobson") has served as Axsome's Chief Operating Officer since March 2020. Before then, he served as the Company's Senior Vice President of Operations at all relevant times.

20. Defendant Cedric O'Gorman ("O'Gorman") served as Axsome's Senior Vice President of Clinical Development and Medical Affairs from before the start of the Class Period to September 2021.

21. Defendant Kevin Laliberte ("Laliberte") served as Axsome's Executive Vice President of Product Strategy from January 2021 to December 2021.

22. Defendants Tabuteau, Pizzie, Jacobson, O'Gorman, and Laliberte are sometimes referred to herein as the "Individual Defendants."

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

24. Axsome and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

25. Axsome is a biopharmaceutical company that engages in the development of novel therapies for CNS disorders in the U.S. The Company is developing, among other product candidates, AXS-07, a novel, oral, rapidly absorbed, multi-mechanistic, and investigational medicine for the acute treatment of migraine.

26. Axsome consistently touted AXS-07's regulatory and commercial prospects in anticipation of the Company's submission of the AXS-07 NDA to the FDA based on the drug's positive results in two Phase 3 trials. However, unbeknownst to investors, the Company's preparation and eventual submission of the AXS-07 NDA was plagued with CMC issues.

Materially False and Misleading Statements Issued During the Class Period

27. The Class Period begins on December 30, 2019, when Axsome issued a press release during pre-market hours, announcing that AXS-07 had met its two regulatory co-primary endpoints in a Phase 3 trial called the MOMENTUM trial for the treatment of migraine. That press release stated, in relevant part, that "[t]he positive results on both co-primary endpoints along with the demonstration of component contribution support the filing of an NDA for AXS-07 in the acute treatment of migraine"; that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine"; and that "Axsome plans to file the NDA in the second half of 2020."

28. The same December 30, 2019 press release also quoted Defendant Tabuteau, who stated, in relevant part: "These data have potentially important implications for patient care based

on the high rate of inadequate response to and patient dissatisfaction with current treatments. With these positive results, we look forward to filing an NDA for AXS-07 in the acute treatment of migraine in 2020."

29. On March 12, 2020, Axsome issued a press release reporting the Company's fourth quarter and full year 2019 results, stating, in relevant part, that "[t]he positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine, which is anticipated in the fourth quarter of 2020"; and that "[t]o support the planned NDA filing of AXS-07 in the acute treatment of migraine, enrollment in a Phase 3 open-label, long-term safety extension study of AXS-07 is ongoing."

30. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's fourth quarter and full year 2020 results. In his prepared remarks, Defendant Tabuteau stated, in relevant part:

> The positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine and we remain on track to file this NDA in the second half of 2020. With . . . two planned NDA filings Axsome is on track to transition to commercial stage potentially as early as next year.

31. Also on March 12, 2020, Axsome 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 provided generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing, stating, *inter alia*, that "the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional . . . [CMC], or other data and information."

32. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Tabuteau and Pizzie certified that

"[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

33. On April 6, 2020, Axsome issued a press release announcing that AXS-07 had met its co-primary endpoints in a second Phase 3 trial called the INTERCEPT trial for the treatment of migraine. That press release quoted Defendant Tabuteau, who stated, in relevant part:

> With INTERCEPT and the previously completed MOMENTUM Phase 3 trial in patients with a history of inadequate response to prior acute treatments, AXS-07 has now been evaluated in two positive well-controlled trials . . . . INTERCEPT strengthens our planned NDA for AXS-07 in the acute treatment of migraine, which remains on track to be submitted to the FDA in the fourth quarter.

34. On May 8, 2020, Axsome issued a press release reporting the Company's first quarter 2020 results, stating, in relevant part:

> As we move towards the submission of two NDAs in the fourth quarter . . . one for AXS-07 in migraine, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.
>
> * * *
>
> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials. A Phase 3, open-label, long-term safety extension study of AXS-07 is ongoing to further support the NDA filing.

35. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's first quarter 2020 results. On that call, in response to an analyst question regarding whether there "[i]s . . . any new clinical data, including . . . CMC activities" for the Company's NDAs, Defendant Tabuteau stated, in relevant part:

> With regards to CMC activities, there are registration batches which are being manufactured now. A good thing for us is that we have been manufacturing our clinical trial supply at commercial scale and also at the same CMO that we're using for commercial production. So, there's no scale up that needs to be done.

> Now, with regards to manufacturing and any kind of science to it, there's always tweaks and experimentation, but I would say that there is no rate-limiting step and there is no extensive experimentation. This is simply manufacturing our registration batches for regulatory purposes.

36. On May 11, 2020, Axsome 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"). That filing provided generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing, stating, *inter alia*, that "in connection with the [CMC] data necessary for our NDA filings, we will need to conduct stability studies and provide stability data to establish appropriate retest or expiration dating period"; and that "[d]uring the course of review, the FDA may also request or require additional CMC, or other data and information, and the development and provision of these data and information may be time consuming and expensive."

37. Appended as exhibits to the 1Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

38. On August 10, 2020, Axsome issued a press release reporting the Company's second quarter 2020 results, stating, in relevant part:

> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials.
>
> Enrollment has been completed in the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-07 in the acute treatment of migraine. More than 700 patients have been enrolled, approximately 450 of whom have been treated with AXS-07 for at least 6 months to date.

39. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's second quarter 2020 results. In his prepared remarks, Defendant Tabuteau stated, *inter alia*:

> Over the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine[.]
>
> * * *
>
> [W]e remain on track to submit the NDA for AXS-07 for the acute treatment of migraine in the fourth quarter. To that end, we have completed enrollment in the Phase 3 open-label safety extension trial of AXS-07 in migraine, which we call the MOVEMENT study to support the planned NDA filing. As we move towards the filing of our NDA[] in the fourth quarter . . . for AXS-07, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.

40. Also on August 10, 2020, Axsome 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 contained the same statements referenced in ¶ 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

41. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

42. The statements referenced in ¶¶ 27-41 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) Axsome's CMC practices were deficient with respect to AXS-07 and its manufacturing process; (ii) as a result, Axsome was unlikely to submit the AXS-07 NDA on its initially represented timeline; (iii) the foregoing CMC issues remained unresolved at the time that the FDA reviewed the AXS-07 NDA; (iv) accordingly, the FDA was unlikely to approve the AXS-07 NDA; (v) as a result of all the foregoing, Axsome had overstated AXS-07's regulatory and commercial prospects; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

43. On November 5, 2020, Axsome issued a press release reporting the Company's third quarter 2020 results. That press release disclosed, in relevant part, that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

44. On this news, Axsome's stock price fell $5.22 per share, or 6.99%, to close at $69.51 per share on November 5, 2020. Despite this decline in the Company's stock price, Axsome securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding CMC issues with the AXS-07 NDA.

45. For example, the same November 5, 2020 press release stated, that "[p]re-submission activities for the Company's NDA for AXS-07 in the acute treatment of migraine are progressing with major NDA-related items on track for completion by year-end."

46. The same November 5, 2020 press release also quoted Defendant Tabuteau, who stated, in relevant part, that "[o]ver the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine, and intensified our commercial launch readiness activities," and that "[w]e anticipate an active next few months as we complete our NDA submission[] for . . . AXS-07[.]"

47. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's third quarter 2020 results. In his prepared remarks, Defendant Tabuteau reiterated that the Company was taking steps to ensure a robust AXS-07 NDA submission, particularly with respect to the drug's manufacturing, stating, in relevant part:

> Switching now to our migraine program with AXS-07. The major MDA related items are on track for completion by year end. We now plan to submit the NDA in the first quarter of 2021 versus previous guidance of the fourth quarter of 2020 in order to allow for inclusion of supplemental manufacturing information. We believe that this approach will enhance the robustness of our submission.

48. On the same call, in response to multiple analyst questions regarding the additional manufacturing information that Axsome submitted to the FDA for the AXS-07 NDA, Defendants Tabuteau and Jacobson assured investors that the additional information was just to ensure a robust submission and did not reflect any manufacturing issues. For example, an exchange with one analyst read, in relevant part:

> **[SVB Leerink Analyst]**
>
> And then the second issue was the – for [AXS-]07. You talked about the NDA in the first quarter, including extra manufacturing information. Can you give us kind of the same sense of confidence that, as - you know, my first question, with respect to what's going on here, may give us a little bit more color and how much we're on top of it. And it's definitely going to be not any more delayed than that?
>
> **[Defendant] Tabuteau**
>
> * * *
>
> So with regards to AXS-07, this is a little bit of a different situation. Here, this is a situation whereby by the end of the year, we will have completed all the major activities, which are needed to file our NDA. And we're on track to do that. And because of the unique manufacturing, behind the mosaic technology, we want to make sure that we have as robust as possible of a submission package.
>
> So we continue to generate data. And the question is, how much do you include. And since, you know, we will be having some data in the early part of the year, we'd love to be able to include that in the package.
>
> But to provide some additional color on that, I'm going to turn it over to [Defendant] Jacobson.
>
> **[Defendant] Jacobson**
>
> Good morning, Marc. So just want to be clear, this is not the result of the manufacturing or stability issue or anything like that. Exactly as [Defendant Tabuteau] said, that we will have data available, that we think would add to the

> submission given us a novel delivery technology. And so that will just allow us to make the package as robust as possible.

49. In response to a similar question from another analyst, Defendant Tabuteau again downplayed issues with respect to AXS-07's manufacturing:

> **Unidentified Analyst**
>
> Thank you for taking our questions. This is Miguel on the line for Joon. Could you provide more specifics on what manufacturing data related to the mosaic platform will be added for AXS-07?
>
> * * *
>
> **[Defendant] Tabuteau**
>
> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very long-term stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

50. Also on November 5, 2020, Axsome 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, 2020 (the "3Q20 10-Q"). That filing contained the same statements referenced in ¶ 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

51. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

52. On March 1, 2021, Axsome issued a press release reporting the Company's fourth quarter and full year 2020 results. That press release quoted Defendant Tabuteau, who represented, in relevant part, that Defendants "had successful pre-NDA meetings with the FDA . . . for AXS-

07 in migraine" and "are nearing submission of the NDA for AXS-07 in the acute treatment of migraine, which is expected early in the second quarter." Similarly, Defendant Tabuteau assured investors that "[o]ur focus for the remainder of the year will be on the regulatory activities surrounding these NDAs, [and] launch readiness to ensure a successful transition to commercialization[.]"

53. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's fourth quarter and full year 2020 results. In his prepared remarks, Defendant Tabuteau reiterated that Defendants were "completing compilation of the [AXS-07] NDA which we expect to submit to the FDA early in the second quarter."

54. On the same call, and in response to an analyst's question regarding why the AXS-07 NDA submission was pushed back to second quarter 2021, Defendant Tabuteau stated: "With regard [AXS-]07 and the NDA filing the team remains on track to complete the filing by the end of the quarter. However, we are waiting on one vendor report which will slip into very beginning of the second quarter and that's the reason[.]"

55. Also on March 1, 2021, Axsome 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, 2020 (the "2020 10-K"). That filing contained the same statements referenced in ¶¶ 31 and 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

56. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

57. On May 10, 2021, Axsome issued a press release reporting the Company's first quarter 2021 results. That press release stated, in relevant part, that "Axsome is compiling the NDA for AXS-07 for the acute treatment of migraine, which is on track for submission to the FDA in the second quarter of 2021."

58. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's first quarter 2021 results. In response to an analyst question regarding "what the gating factors are in terms of getting th[e AXS-07 NDA] submission into the FDA" given that Axsome had pushed back its regulatory timeline multiple times, Defendant O'Gorman stated, in relevant part: "With regards to AXS-07, we're very much on track to file the NDA this quarter, as we've previously stated, and there really isn't any update there. The team is working diligently to make sure that we have a timely, but also a quality filing."

59. Also on May 10, 2021, Axsome 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, 2021 (the "1Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

60. Appended as exhibits to the 1Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

61. On August 9, 2021, Axsome issued a press release reporting the Company's second quarter 2021 results. That press release quoted Defendant Tabuteau, who noted that although the FDA had identified deficiencies with an NDA for the Company's AXS-05 product candidate,

"[o]ur other programs continue to advance" and "[w]e successfully filed our NDA for AXS-07 for the acute treatment of migraine in the second quarter[.]"

62. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's second quarter 2021 results. In response to an analyst question regarding whether AXS-07 is manufactured at the same facility as AXS-05, Defendant Jacobson stated:

> So for the manufacturing process for AXS-07, that actually is a bit more complicated and there are two facilities that we utilized for the manufacturer of the drug product. The drug -- the API's are also available under open DMF too in the U.S. And of the two facilities that we used for drug product manufacturing, one of them is the same that we used for AXS-05.

63. Also on August 9, 2021, Axsome 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, 2021 (the "2Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

64. Appended as exhibits to the 2Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

65. On September 14, 2021, Axsome issued a press release announcing that the FDA had accepted the AXS-07 NDA, stating, in relevant part:

> [T]he [FDA] has accepted for filing the Company's [NDA] for AXS-07 for the acute treatment of migraine, and has set a [PDUFA] target action date of April 30, 2022 for the NDA. AXS-07 (MoSEIC™ meloxicam-rizatriptan) is a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for migraine.
>
> "The FDA's acceptance of the NDA for AXS-07 is an important milestone for Axsome as it brings us closer to potentially making this multi-mechanistic treatment available to migraine patients in need," said [Defendant] Tabuteau, MD, Chief Executive Officer of Axsome. "We look forward to continued interactions with the FDA during the review process."

> The NDA is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials, which demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls.

66. On November 8, 2021, Axsome issued a press release reporting the Company's third quarter 2021 results. That press release quoted Defendant Tabuteau, who represented, in relevant part:

> Over the past several months we have continued to advance our differentiated late-stage CNS product candidates aimed at meaningfully improving the lives of patients . . . . [T]he NDA for AXS-07 in migraine was accepted, positioning Axsome to potentially commercialize two new treatments in the near to intermediate term for patients living with . . . serious CNS disorders[.]

67. The same November 8, 2021 press release also advised investors, in relevant part, that "[t]he FDA notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility [for the AXS-07 NDA] . . . prior to the PDUFA date[.]"

68. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's third quarter 2021 results. On that call, in response to an analyst question regarding the FDA's delayed inspection of the contract manufacturing facility for the AXS-07 NDA, Defendants Tabuteau and Laliberte downplayed issues with manufacturing on the drug's regulatory timeline. That exchange read, in relevant part:

> **[SVB Leerink Analyst]**
>
> Just one quick question on the migraine, can you just help us understand, did you say that one of the two manufacturing sites might not be able to be signed off on by the PDUFA date? So you're implying that one could be and is one enough? Do you both have to be filed? I was a little confused by your comment. Thank you.
>
> **[Defendant] Tabuteau**

> Yes. So it's – I'll turn it over to [Defendant Laliberte], who will respond to that. But I think it's pretty straightforward in terms of what the FDA is trying to give a sense on there.
>
> **[Defendant] Laliberte**
>
> Thanks for that question. So there are obviously multiple manufacturing sites involved in the process for AXS-07. The FDA notified us that one specific manufacturing location that is based in the United States is required to have an inspection prior to them, as part of the review process.
>
> And then they did notify us that because of COVID-related restrictions, that may be in jeopardy of happening before the PDUFA date. So it's just this one manufacturer based in the United States that they specifically notified us of in their communication.

69. Also on November 8, 2021, Axsome 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, 2021 (the "3Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

70. Appended as exhibits to the 3Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

71. On March 1, 2022, Axsome issued a press release reporting the Company's fourth quarter and full year 2021 results. That press release stated, in relevant part:

> Axsome's NDA for AXS-07 for the acute treatment of migraine is currently under review by the FDA with a PDUFA target action date for the NDA of April 30, 2022. The FDA previously notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility, located in the United States, prior to the PDUFA date. Axsome has since been informed by the FDA that it does not anticipate any issues with completing this facility inspection prior to the AXS-07 PDUFA date.

72. The same March 1, 2022 press release also quoted Defendant Tabuteau, who represented, in relevant part, that "2021 was a year of continued progress which has put us in a position to potentially launch two new investigational medicines for patients living with depression and migraine," including "the April 30 PDUFA date for our NDA for AXS-07 in the acute treatment of migraine [that] is approaching."

73. That same day, Axsome 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"). That filing contained substantively the same statements referenced in ¶¶ 31 and 36, *supra*, providing generic, boilerplate representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

74. Appended as exhibits to the 2021 10-K were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Tabuteau and Pizzie.

75. The statements referenced in ¶¶ 43 and 45-74 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) Axsome's CMC practices were deficient with respect to AXS-07 and its manufacturing process; (ii) the foregoing CMC issues remained unresolved at the time that the FDA reviewed the AXS-07 NDA; (iii) accordingly, the FDA was unlikely to approve the AXS-07 NDA; (iv) as a result of all the foregoing, Axsome had overstated AXS-07's regulatory and commercial prospects; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

76. On April 25, 2022, during pre-market hours, Axsome filed a current report on Form 8-K with the SEC, which disclosed:

> On April 22, 2022, Axsome . . . was informed by the [FDA] that [CMC] issues identified during the FDA's review of the Company's [NDA] for its AXS-07 product candidate for the acute treatment of migraine are unresolved. Based upon the time remaining in the NDA review cycle, the Company expects to receive a [CRL] with respect to this NDA on or about the [PDUFA] target action date of April 30, 2022.

77. On this news, Axsome's stock price fell $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022.

78. 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.

Post-Class Period Developments

79. On May 2, 2022, Axsome issued a press release announcing that it received a CRL from the FDA regarding the AXS-07 NDA for the acute treatment of migraine. That press release stated, in relevant part:

> [T]he Company has received a [CRL] from the [FDA] regarding its [NDA] for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07.
>
> The principal reasons given in the CRL relate to [CMC] considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

80. 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 Axsome 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.

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

82. 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.

83. 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.

84. 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 Axsome;
- whether the Individual Defendants caused Axsome 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 Axsome 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.

85. 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.

86. 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;
- Axsome 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 Axsome 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.

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

88. 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)

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

90. 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.

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

92. 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 Axsome 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 Axsome's finances and business prospects.

93. By virtue of their positions at Axsome, 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.

94. 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 Axsome, the Individual Defendants had knowledge of the details of Axsome's internal affairs.

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

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

97. 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.

98. 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)

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

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

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

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

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

104. 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 Axsome.

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.