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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

CITY OF BIRMINGHAM RELIEF AND RETIREMENT SYSTEM AND OHIO CARPENTERS' PENSION FUND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS INC., STEPHEN R. DAVIS, and SRDJAN (SERGE) R. STANKOVIC,

Defendants.

Civ. No. 3:21-CV-00762-WQH-NLS

CLASS ACTION

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Lead Plaintiff City of Birmingham Relief and Retirement System ("Birmingham") and additional Plaintiff Ohio Carpenters' Pension Fund ("Ohio Carpenters") (collectively, "Plaintiffs"), individually and on behalf of all others similarly situated, by their undersigned attorneys, for their complaint against Defendants, allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and upon information and belief as to all other matters based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, Defendants' filings with the United States Securities and Exchange Commission ("SEC"), press releases and news articles regarding defendant Acadia Pharmaceuticals Inc. ("Acadia" or the "Company"), and analysts' reports and advisories about the Company and the industry within which it operates. Plaintiffs believe 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 (the "Class") consisting of all persons and entities other than Defendants that purchased or otherwise acquired Acadia common stock between September 9, 2019 and April 4, 2021, inclusive (the "Class Period"). The Action seeks to recover damages caused by Defendants' violations of 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, its Chief Executive Officer ("CEO"), and its President/Head of Research & Development.

2. Acadia is a biopharmaceutical company that focuses on the development and commercialization of small molecule drugs that seek to address unmet medical needs in central nervous system disorders. The most valuable drug

from a commercial perspective, that Acadia has developed is pimavanserin, which the Company touts as a treatment for dementia-related psychosis ("DRP"). DRP occurs in patients with a *variety* of different types of dementia, including Alzheimer's disease ("Alzheimer's" or "AD"), dementia with Lewy bodies ("DLB"), vascular dementia ("VaD"), frontotemporal dementia ("FTLD"), and Parkinson's disease dementia ("PDD"). In April 2016, the U.S. Food and Drug Administration ("FDA") approved pimavanserin for the treatment of hallucinations and delusions associated with the type of psychosis associated with Parkinson's disease dementia, known as Parkinson's disease psychosis ("PSP").

3. After obtaining approval to use pimavanserin to treat PSP, Defendants sought to obtain FDA approval for greatly expanded use of the drug to treat other main types of DRP, which in turn promised to dramatically increase the drug's commercial value (as it would allow Acadia to market the drug to treat patients suffering from types of DRP other than PSP). In particular, Defendants launched what they touted as a significant Phase III trial, known as the HARMONY trial (the "Harmony Study"), to further study the drug's effectiveness in a range of DRP patients.

4. On September 9, 2019 (the first day of the Class Period), Acadia announced positive results for the Harmony Study. Indeed, the Company announced that it was stopping the Harmony Study early because its results were so overwhelmingly favorable. For example, Defendants represented that the Harmony Study had demonstrated "a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis," and therefore established a firm foundation for Acadia to file a Supplemental New Drug Application ("sNDA") that would support FDA approval of pimavanserin as a treatment for *all* forms of dementia-related psychosis. As Defendant Stankovic, Acadia's President and Head of Research and Development,

stated: "We are very excited that today's results bring us one step closer to the potential of offering patients with dementia-related psychosis a critically needed treatment option. We look forward to speaking with the FDA about a supplemental new drug application to support pimavanserin for the treatment of dementia-related psychosis."

5. Moreover, to further assure investors that the Harmony Study provided a strong foundation for obtaining expanded use approval, Defendants represented that the FDA had already blessed the adequacy of the study's design for purposes of obtaining such lucrative approval. For example, on September 9, 2019, Defendant Stankovic stated: "I would also like to remind you that at the end of [our] Phase II meeting with FDA, we confirmed that for our [s]NDA submission [for pimavanserin] in DRP, ***we could rely on a single, well-controlled study*** whose results were both statistically and clinically very persuasive." Similarly, on February 26, 2020, Stankovic stated "***The pivotal HARMONY study results will be the basis of the sNDA submission, which was previously agreed upon at the end of Phase II meeting.***" [Emphasis added]. Thereafter, Defendants repeatedly continued to stress both the "positive" results of the Harmony Study, and that the FDA had already signed off on the adequacy of that study's design for purposes of obtaining the broader use authorization that the Company wanted.

6. In response to these positive reports, the price of Acadia's common stock shot up more than 63%, closing at $38.85 on September 9, 2019.

7. Unfortunately for investors, however, Defendants' repeated assurances that the FDA had agreed that the design of the Harmony Study was adequate for such purposes were materially false and misleading -- and failed to disclose that in fact the Harmony Study's design was so flawed that even the kinds of facially "positive results" that it produced could not support FDA approval of pimavanserin for additional types of DRP beyond PSP (which was the primary purpose for

conducting the Harmony Study in the first place). Simply stated, because patients with Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia and frontotemporal dementia, respectively, have *different* (if not widely varying) profiles, there can be no *a fortiori* assurance that patients in these different groups will respond to the same drug in the same way, either in terms of efficacy or safety.

8. As Defendants knew or recklessly disregarded even before launching the Harmony Study, that Harmony Study simply was not reasonably designed to contain a sufficient number of patients in any of its non-PSP subgroups to allow the FDA (or any reasonable biostatistician) to conclude, based on statistically significant evidence, that pimavanserin was an effective treatment for patients in those subgroups. Instead, the Harmony Study was largely populated by patients suffering from dementia associated with Parkinson's disease -- the condition for which pimavanserin was *already* FDA-approved. Accordingly, because the study was "under-powered" from the outset for purposes of generating the kinds of results at the relevant patient subgroup levels that would support FDA approval to additional types of DRP patients, Defendants knew or recklessly disregarded that the Harmony Study would have to produce truly extraordinary results within the relevant sub-group populations to support approval for those subgroups. And when the Harmony Study results became available, the data for the non-PSP subgroups was actually disappointing, whether viewed by individual subgroup or based on a pooling of all such non-PSP subgroups. In sum, contrary to Defendants' representations, the Harmony Study's results were not "positive" in terms of supporting the primary purpose of the trial as it had failed to establish a statistically significant benefit for non-PSP patients, and far from having obtained any assurances from the FDA that the Harmony Study's design was likely sufficient to obtain approval, in fact no such assurances had ever been given. And Defendants knew or recklessly disregarded

throughout the Class Period that the Company's high risk gamble on the Harmony Study's underpowered design would likely not support expanded FDA approval of pimavanserin.

9. The undisclosed truth began to emerge on March 8, 2021, when Acadia issued a press release after the close of the market that provided an update on its pimavanserin sNDA. That release stated "that the Company received a notification from the [FDA] on March 3, 2021, stating that, as part of its ongoing review of the Company's [sNDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." In response, Acadia's common stock price fell $20.76 per share, or 45.35%, to close at $25.02 per share on March 9, 2021.

10. Shortly thereafter, on April 5, 2021, Acadia issued a press release announcing that the Company had received a Complete Response Letter ("CRL") from the FDA which indicated that the sNDA could ***not*** be approved in its current form. As the press release stated, "the [FDA Division of Psychiatry], in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval."

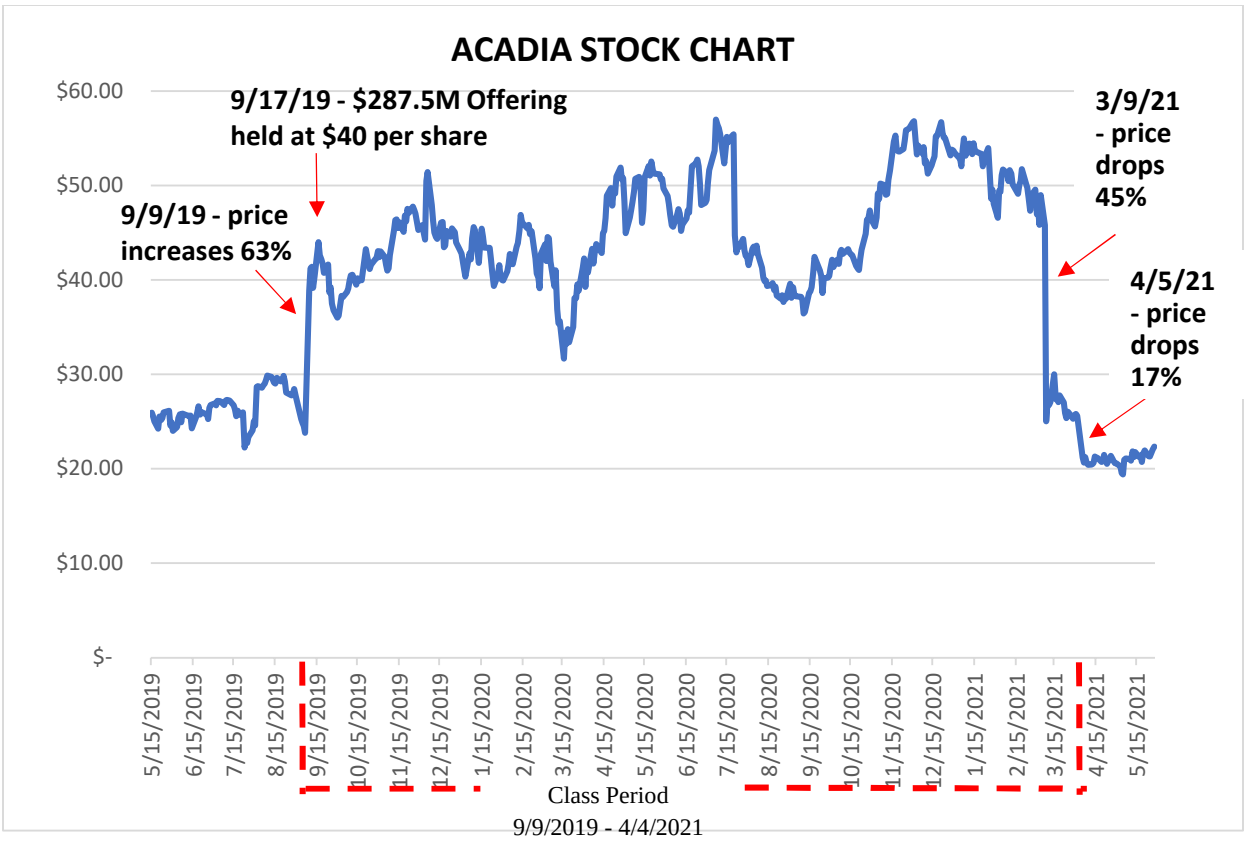
11. In response, Acadia's common stock price fell a further $4.41 per share, or 17.23%, to close at $21.18 per share on April 5, 2021.

12. Tellingly, as of the date of this complaint, Defendants have yet to release a copy of the actual text of the CRL, presumably because doing so would undermine their efforts to conceal the extent to which they misled investors as to the alleged assurances they had supposedly received from the FDA.

13. Although investors suffered devastating losses on their Class Period purchases as a result of Defendants' wrongful conduct, Acadia and both of the Individual Defendants successfully sold hundreds of millions of dollars of worth of

Acadia common stock at grossly inflated prices that were roughly twice what they were prior to the commencement of the fraudulent scheme. Specifically: (1) Defendant Acadia sold $287.5 million worth of its common stock just the week after the start of the Class Period; (2) Defendant Stephen Davis ("Davis"), Acadia's CEO, sold roughly $24.8 million worth of his personal holdings of Acadia shares during the Class Period; and (3) Defendant Srdjan (Serge) Stankovic ("Stankovic"), Acadia's President and Head of Research & Development, sold approximately $18.9 million of his personal holdings of Acadia common stock during the same period. As further detailed below, these insider sales were highly unusual in terms of both their size and timing.

14. The extent to which Defendants' were able to capitalize on their false and misleading statements by pumping up the price of Acadia shares – and then maintaining those artificially inflated prices during the Class Period – is illustrated by the chart below. Indeed, the Company's average share price during the Class Period was roughly double what it had been in the 12 months immediately preceding the Class Period:



15. By this Action, Plaintiffs, on behalf of themselves and the Class they seek to represent, seek to recover damages for the significant losses they have suffered as a result of Defendants' wrongful acts and omissions.

JURISDICTION AND VENUE

16. 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).

17. 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.

18. 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). Acadia 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.

19. 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

20. Plaintiff Birmingham, as set forth in its previously-filed certification, acquired Acadia common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

21. Plaintiff Ohio Carpenters, as set forth in its previously-filed certification, acquired Acadia common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

22. Defendant Acadia is a Delaware corporation with principal executive offices located at 12830 El Camino Real, Suite 400, San Diego, California 92130. The Company's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "ACAD."

23. Defendant Davis has served as Acadia's Chief Executive Officer and a member of the Company's Board of Directors since September 2015. He joined Acadia in July 2014 as Executive Vice President, Chief Financial Officer. Davis was an architect and primary beneficiary of the scheme alleged herein. Davis made many false statements during the Class Period and sold approximately $24.8 million in stock at prices that were massively inflated by Defendants' misstatements.

24. Defendant Stankovic has served as Acadia's President and Head of Research and Development since November 2018. Prior to serving as President, Stankovic was Acadia's Executive Vice President, Head of Research and Development, from November 2015 through November 2018. Stankovic was an architect and primary beneficiary of the scheme alleged herein. Stankovic made

many false statements during the Class Period and sold $18.9 million in stock at prices that were massively inflated by Defendants' misstatements. Additionally, as the Head of Research and Development at all relevant times, Stankovic was aware that the FDA had never agreed to Acadia's plan for the sNDA. Stankovic also was fully aware of the defects in the Harmony Study and the problematic data generated by the study.

25. Defendants Davis and Stankovic are sometimes referred to herein as the "Individual Defendants."

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

SUBSTANTIVE ALLEGATIONS

BACKGROUND

27. Acadia is a biopharmaceutical company that focuses on the development and commercialization of small molecule drugs that address unmet medical needs in central nervous system ("CNS") disorders. The Company is developing pimavanserin as a treatment for DRP and as an adjunctive treatment for schizophrenia, as well as an adjunctive treatment for major depressive disorder.

28. As of December 31, 2019, the Company had 503 employees, with approximately 160 employees engaged in research and development activities. In 2020, the Company added 98 employees for a total of 601 as of December 31, 2020.

29. Acadia's only product is its novel drug, NUPLAZID (pimavanserin). Pimavanserin is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5-HT2A receptors.

30. Acadia owns worldwide commercialization rights to pimavanserin.

31. In April 2016, the FDA approved pimavanserin for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. The Company launched the product in the United States in May 2016.

32. The PDP approval has been a very successful income stream for the Company. The Company's net product sales consist of sales of pimavanserin only, its first and only commercial product to date.

33. In 2020, Acadia had net product sales of $441.8 million, representing a 30% year-over-year growth. In the preceding years since obtaining FDA approval, net product sales were: $339.1 million (2019); $223.8 million (2018); $124.9 million (2017); and $17.3 million (2016).

34. The Company expected 2021 net sales (PDP only) to be between $510 million and $550 million, representing 20% year-over-year growth at the midpoint of the range. For the first three quarters of 2021, the Company has had net product sales of $353.4 million.

35. The Company has been actively working on expanding pimavanserin's label to encompass all DRP since at least 2017. In October 2017, the Company announced that the FDA had granted Breakthrough Therapy Designation to pimavanserin for the treatment of DRP.

36. Expanding the label would be of significant commercial value to the Company. Analysts saw U.S. peak sales increasing to $2.4 billion in DRP (including PDP) if the label was expanded to include a broad indication for DRP.

37. DRP is prevalent across dementias and is about tenfold the size of PDP in terms of addressable population.

38. Around 8 million people in the United States are living with dementia and studies suggest that approximately 30% of people with dementia, or 2.4 million people, experience dementia-related hallucinations and delusion.

39. DRP occurs in many types of dementia, including: Alzheimer's disease; Dementia with Lewy bodies; Parkinson's disease dementia; Vascular dementia; and Frontotemporal dementia.

40. Alzheimer's is by far the most prevalent, accounting for 60 to 80 percent of all dementia. More than 6 million Americans are living with Alzheimer's. By 2050, this number is projected to rise to nearly 13 million. Psychosis affects between 40 and 50 percent of people with Alzheimer's at some point over the course of the disease.

41. To date, no pharmacological agents are approved by the U.S. Food and Drug Administration (FDA) to treat DRP.

42. PSP and DRP are progressive diseases and patients need to stay on therapy for their entire life. Their symptoms do not improve absent treatment. Thus, patients need to be on therapy both in the acute stage as well as long term.

43. On June 3, 2020, Acadia submitted its sNDA for pimavanserin for the treatment of hallucinations and delusions associated with DRP.

44. The sNDA was based on three studies described herein: principally, the Harmony Study; with further support from the Phase III "-020 Study," and the Phase II "-019 Study."

45. The -020 Study was initiated in July 2011 and evaluated the efficacy, tolerability and safety of pimavanserin in patients with PSP. A total of 199 patients were enrolled in the study and randomized on a one-to-one basis to receive either 40 mg of pimavanserin or placebo once-daily for six weeks, following a two-week screening period including brief psycho-social therapy. Patients also received stable doses of their existing anti-Parkinson's therapy throughout the study. The -020 Study was a multi-center, double-blind, placebo-controlled study, with 62 locations in the U.S. and 1 in Canada. The mean age of patients in the -020 Study was 72.

46. In November 2012, the Company announced positive top-line results for the -020 Study. Pimavanserin met the primary endpoint in the -020 Study by demonstrating highly significant antipsychotic efficacy (p=0.001). Pimavanserin also met the secondary endpoint for motoric tolerability. These results were supported by a highly significant improvement in the secondary measure of antipsychotic efficacy. In addition, clinical benefits were observed in exploratory efficacy measures of sleep and caregiver burden. Consistent with previous studies, pimavanserin was generally safe and well tolerated in the -020 Study.

47. The -020 Study was the primary basis for the FDA's 2016 approval of pimavanserin for the treatment of PSP.

48. The -019 Study, initiated in November 2013, enrolled 181 patients and was conducted at a single site – a network of 134 care homes in London, United Kingdom. The -019 Study was a double-blind, placebo-controlled exploratory trial designed to evaluate the efficacy and safety of pimavanserin as a treatment for patients with Alzheimer's disease psychosis ("ADP"). Following a screening period, patients were randomized on a one-to-one basis to receive either pimavanserin or placebo once-daily. The primary endpoint of the study was antipsychotic efficacy from baseline to week six of dosing. The study also assessed

additional secondary endpoints, including the cognitive status of patients and the durability of response to pimavanserin, through week twelve of dosing.

49. In December 2016, the Company announced positive top-line results from the -019 study. Pimavanserin demonstrated efficacy on its primary endpoint with a 3.76 point improvement in psychosis at week six compared to a 1.93 point improvement for placebo, representing a statistically significant treatment improvement (p=0.0451). Baseline mean scores for the pimavanserin and placebo treated groups were 9.52 and 10.00, respectively. Pimavanserin was generally well tolerated and the safety profile was consistent with what had been observed in previous studies. The most common adverse events reported were falls, urinary tract infection and agitation. The mortality rate was the same in the pimavanserin and placebo treatment groups. Over the course of 12 weeks of treatment, pimavanserin did not impair cognition as measured by the Mini-Mental State Examination, or MMSE, score and was similar to placebo. On the secondary endpoint of mean change at week 12, pimavanserin maintained the improvement on psychosis observed at the week six primary endpoint, but did not statistically separate from placebo. The mean age of patients in the -019 Study was 86 years.

50. Following the -019 Study on ADP, in mid-2017, Acadia had an End-of-Phase II meeting with the FDA. At that meeting, according to the Company, Acadia proposed a plan for a single Phase III study that would support approval not for an indication of pimavanserin for ADP, but for a broader indication of pimavanserin for DRP.

51. A driver of the decision to seek approval for DRP rather than ADP (which had been the focus of the Phase II -019 Study) was the fact that the Company had more competition in the ADP treatment space.

52. In October 2017, the Company initiated the Harmony Study, a pivotal Phase III study, to assess pimavanserin as a treatment for DRP. This was a much

broader indication than the already FDA-approved PDP indication and was also much broader than the ADP indication that was the focus of the -019 Study.

53. The Harmony Study was a double-blind, placebo controlled relapse prevention study. It followed patients until they had a relapse, defined by hospitalization as a result of DRP, deterioration of dementia symptoms, withdrawal from the study due to lack of efficacy, or use of another antipsychotic medication.

54. Relapse prevention studies generally have a higher probability of success than acute studies.

55. The Harmony Study took place at 83 study locations, scattered across the United States, Europe, and Chile, and enrolled 392 participants with dementia who had suffered from symptoms of psychosis for at least the previous two months. Following a 12-week open-label period, participants who responded were broken into two groups for the following 26 weeks, in which one received a placebo and the other pimavanserin.

56. Acadia, Davis, and Stankovic possessed data from the Harmony Study starting in at least early September 2019. The primary completion date of the Harmony Study, the date on which the last participant in the study was examined to collect final data for the primary outcome measure, was July 31, 2019.

57. On September 9, 2019, Acadia issued a press release entitled "ACADIA Pharmaceuticals Announces Pivotal Phase 3 HARMONY Trial Stopped Early for Positive Efficacy as Pimavanserin Meets the Primary Endpoint in Patients with Dementia-Related Psychosis." Therein, Defendants claimed that the Harmony Study was stopped early due to positive efficacy at the pre-planned interim analysis.

58. The purportedly positive results from the Harmony Study were that pimavanserin significantly reduced the risk of a relapse. Acadia represented that the primary endpoint was time to relapse in the double-blind period as represented by the Kaplan-Meier curve and the hazard ratio. Pimavanserin met the primary

endpoint of the study by significantly reducing the risk of relapse of psychosis by 2.8 fold compared to placebo (HR = 0.353; one-sided p=0.0023).

59. Eight days later, on September 17, 2019, the Company announced a proposed follow-on offering of approximately $250 million of common stock.

60. On September 20, 2019, the follow-on offering closed and Acadia sold 7,187,500 shares at a price of $40 per share, for gross proceeds totaling $287.5 million.

61. On October 3. 2019, Acadia announced that it would present the Harmony Study results at the 12th Clinical Trials on Alzheimer's Disease ("CTAD") Meeting in December 2019, in San Diego, California, as it had been accepted for a late-breaking oral presentation.

62. On December 4, 2019, Acadia presented the Harmony Study's top-line results. In connection with this presentation, the Company released the full data set of the Harmony Study.

63. In the first quarter of 2020, Acadia had a pre-sNDA meeting with the FDA to discuss the Company's planned submission of the DRP sNDA.

64. On June 3, 2020, Acadia submitted the sNDA for DRP.

The Undisclosed Facts

65. Gaining FDA approval is no small feat. The drug approval process takes place within a structured framework that includes: (1) analysis of the target condition and available treatments; (2) assessment of benefits and risks from clinical data; and (3) strategies for managing risks. FDA physicians and scientists review drug research and labeling information on how to use the drug. If the findings show the drug's benefits outweigh its known risks — and that the drug can be manufactured in a way that ensures a quality product — the drug is approved and can be marketed in the U.S.

66. Pimavanserin was the first and only drug indicated specifically to treat patients suffering from Parkinson's disease psychosis, which the National Parkinson Foundation estimated at the time of approval to be 40 percent of the "one million people in the United States and from four to six million people worldwide" suffering from Parkinson's disease.

67. However, FDA approval does not mean that use of the drug is not without risk. To that end, in approving pimavanserin for PDP, the FDA asked that Acadia include a black-box warning, its strictest warning, on the drug's label, warning of increased mortality in elderly dementia patients and explicitly indicating that "*Nuplazid is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.*" Thus, any use of pimavanserin to treat hallucinations and delusions not associated with Parkinson's is "off-label."

68. "Off-label" use is of concern when there is evidence on the low effectiveness or high risks associated with the use of a drug for a non-approved condition, and yet, it is regularly used. This type of off-label use is most common in psychiatry and is particularly of concern in patients suffering from dementia, as such use has been associated with increased risk of death.

69. Cognizant of the risks associated with "off-label" use, the fact that dementia affects approximately 8 million people in the U.S., of which an estimated 2.4 million people suffer from dementia-related hallucinations and delusions, both of which are expected to grow as the population ages, Acadia sought to expand the use of pimavanserin beyond PDP by submitting its sNDA for the treatment of hallucinations and delusions associated with all types of DRP.

70. The problem is that dementia-related psychosis can be caused by a wide variety of very different underlying conditions, including Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and

frontotemporal dementia spectrum disorders. And, the patient profile of individuals with these conditions varies widely with different patient groups responding to different treatments and facing different health and safety issues. For example, patients with LBD or Alzheimer's disease are more likely to have visual misperceptions and hallucinations than FTLD patients, where delusions of misidentification occur more frequently. Furthermore, patients with FTLD are more likely than those with any other pathology to report paranoid delusions, as well as delusions that were self-elevating, including grandiosity and erotomania.

71. Making matters even more complicated is the fact that not only does the neurobiology of psychosis in different neurodegenerative diseases like PD, AD, and FTLD differ, there is notable heterogeneity even among a single class of neurogenerative diseases like FTLD. Thus, bundling different types of DRP under one umbrella is exceptionally complex.

72. Notwithstanding these significant differences, Acadia set out to expand pimavanserin's use across this broad population of patients and submitted to the FDA data collected primarily from its Harmony Study, supplementing that with data from the -019 Study focused solely on patients suffering from Alzheimer's disease psychosis. Neither set proved to be persuasive, which Defendants knew or should have known would be the case long before filing the sNDA.

A. The Design of the Harmony Study was Patently Flawed

73. Defendants knew that the Harmony Study did not effectively take into account the disparate nature of the individuals that Acadia was seeking approval to treat. Rather, there were insufficient numbers of patients for each subgroup analyzed, making it extremely difficult to determine whether pimavanserin was an effective treatment across the population of those suffering from DRP.

74. Specifically, the Harmony Study enrolled 392 patients suffering from the five most common forms of dementia-related psychosis, each of whom entered

the 12-week, open-label treatment phase. 41 patients in this original set were withdrawn for administrative reasons while 134 patients discontinued the trial early with 70 citing a lack of response, 27 suffering an adverse event, 17 withdrawing consent, and 20 others leaving for other reasons, including failing to adhere to the trial regimen, violating a protocol or receiving prohibited medication.

75. With respect to each subgroup, the distribution of dementia diagnoses was as follows: 66.3% of the patients, or approximately 260 people, had their dementia identified as Alzheimer's disease related; 15.1%, or approximately 59 people, had their dementia identified as Parkinson's disease related; 9.7%, or approximately 38 people, had vascular dementia; 7.1%, or approximately 28 people, had dementia with Lewy bodies; and 1.8%, or approximately 7 patients, had frontotemporal dementia.

76. This distribution is notable for two reasons. First, it shows that the second largest subgroup in the entire study, a study Defendants put forward to extend pimavanserin's use into new indications, consists of patients suffering from Parkinson's disease dementia, a condition pimavanserin is *already* approved for.

77. Second, it shows that the vascular dementia, dementia with Lewy bodies and frontotemporal dementia subgroups, represented by a mere 73 patients, and each objectively lacked sufficient numbers to demonstrate efficacy, particularly given the millions of patients in the U.S. alone suffering from dementia-related psychosis caused by these underlying conditions.

78. By any measure, the Company knew these facts in September 2019 when the trial was stopped for purportedly "positive" interim results, in December 2019 when the Company released the full data set as part of its presentation at CTAD 2019, and in June 2020 when the Company submitted its sNDA to the FDA relying significantly on these data to try to expand pimavanserin's use and modify its black-box warning.

B. The Subgroup Data Acadia Submitted to the FDA in Connection with the sNDA was Itself Weak

79. Even the limited data the Company possessed on each subgroup was poor and demonstrated a lack of efficacy, dooming the Company's sNDA from the outset, if not long before.

80. Again, as part of its sNDA submission, Acadia submitted data from both the Harmony Study and the -019 Study, which was focused solely on patients suffering from Alzheimer's disease psychosis.

81. In the Harmony Study, the supposed "positive" overall results were powered by a surplus of individuals with Parkinson's disease dementia, the condition for which pimavanserin was already approved, skewing the results in favor of pimavanserin.

82. For example, in the double-blinded portion of the study, a 43.3% placebo-adjusted improvement in relapse rate was observed in PDD patients, which lead to a 15.7% improvement observed among all patients enrolled in the study. However, when PDD patients were removed from the overall group, the improvements observed in relapse rate of all the other subgroups combined dramatically declined to 9%, which effectively equaled the result observed in the Harmony Study's largest subgroup, Alzheimer's.

83. In other words, the Harmony Study's data showed that, despite the small sample size, the drug was actually ineffective or in some cases less effective (favoring the placebo) in the subgroups Acadia was seeking new approval for, further underscoring the deficiencies in the Harmony Study. Take for instance the patients suffering from vascular dementia. Seventeen percent of those patients suffered a relapse irrespective of whether they were given pimavanserin or a placebo. This indicates that the drug provided no benefit to patients suffering from this particular condition. Likewise, no benefit was observed in patients with

frontotemporal dementia, as 100% of those enrolled in this double-blinded portion of the study suffered a relapse on pimavanserin compared to 0% of those given the placebo. Tellingly, even in the AD cohort, statistical significance was missed with 13% of patients given pimavanserin suffering a relapse, compared to 23% of patients provided the placebo. Consequently, the Harmony Study's "success" was clearly driven by the PDD patients it (improperly) included.

84. What is more, Defendants knew that the Harmony Study trial data was damaging, especially without the PDD data upon which they relied and because the subgroups were too small, so they offered supplemental data to bolster their sNDA submission from the -019 Study on Alzheimer's disease psychosis. Unfortunately, this data was also problematic.

85. First, patient heterogeneity continued to be an issue. Again, as an example, pimavanserin demonstrated particular effects on visual hallucinations in Alzheimer's patients, but any beneficial effect it might have for people with Lewy body pathology were not recognized in this trial.

86. Second, the -019 Study was predicated on a single center study with no type 1 error control of secondary endpoints in which certain "protocol deviations" occurred, including the administration of "prohibited medications" to patients enrolled in the study, which tainted the results.

87. Third, the -019 Study's designation of a primary efficacy outcome at six weeks, despite continuing double-blinded treatment for 12 weeks, led to a distorted picture of the treatment's efficacy (and a hasty conclusion). Specifically, the primary outcome for the -019 Study was the Neuropsychiatric Inventory-Nursing Home version (NPI-NH) psychosis score (*i.e.*, the sum of the hallucinations and delusions scale scores) at six weeks of treatment. At six weeks, according to the Company's data set, which was presented in full in the *Journal of Prevention on Alzheimer's Disease* in August 2018, AD patients on pimavanserin observed a

change in NPI–NH psychosis score of –3.76 points [SE 0.65] while patients given the placebo only saw a change in NPI–NH psychosis score of –1.93 points [0.63]. According to Defendants, this was "statistically significant."

88. But this result was a mirage. What the data actually showed after continuing to treat patients until twelve weeks was that Acadia did not observe any effect on the NPI–NH psychosis scale at any other time during the 12-week trial. Therefore, had the primary outcome been specified for 12 weeks (which is typical of trials with antipsychotics), pimavanserin would likely not have been considered efficacious at all—a particularly meaningful point as it undercuts the likelihood that pimavanserin could be approved for AD.

89. And, finally, an assessment of the patient profile of the -019 Study showed that 17 of 18 secondary and exploratory outcomes and six of seven subgroup analyses did not demonstrate evidence of efficacy, even though the Company at the time cherry-picked a finding that there was a significant effect that favored pimavanserin within a subgroup of patients with more severe symptoms.

90. Despite Defendants' efforts to highlight the best results and interim (albeit fleeting) efficacy within the AD population, in fact, the -019 Study's poorly analyzed data and poor design, among the many other shortcomings noted above, rendered the dataset far from "supportive."

91. Thus, by any measure, Defendants knew, despite their repeated claims suggesting otherwise, that the sNDA was doomed.

C. With Poorly Designed Studies Delivering Disappointing Data, Defendants Fabricate the Existence of an "Agreement" with the FDA on Acadia's Plan for its sNDA

92. Contrary to Defendants' claim that the FDA and Acadia agreed to the pivotal Harmony Study's design, targeting a broad DRP patient population analyzed as a single group, during the end of Acadia's Phase II meeting (after the -019 Study), no such agreement actually existed.

93. For purposes of background, in 1962, growing concerns in Congress about misleading and unsupported claims made by pharmaceutical companies about their drug products, in combination with high drug prices, led to enactment of Public Law 78-871, also referred to as the Kefauver-Harris Drug Amendments of 1962. These amendments to the Food, Drug, and Cosmetic Act of 1937 (the "FD&C Act") required drug manufacturers for the first time to submit to and obtain approval from the FDA of a New Drug Application ("NDA") demonstrating the safety and efficacy of their drugs before marketing them.

94. FDA approval of a NDA, or a supplemental NDA seeking approval of a new use, is conditioned in part on demonstration of effectiveness by "substantial evidence," defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." FD&C Act §505(d) (21 U.S.C. §355(d)).

95. Based on the language and legislative history of the statute, the FDA has generally interpreted Congress's intent in requiring "adequate and well-controlled investigations" as referring to both the quality and quantity of data required to demonstrate effectiveness (S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962)), with at least two adequate and well-controlled investigations demonstrating efficacy for a particular use required for NDA or sNDA approval. The FDA's position has been upheld in actions brought by manufacturers challenging this interpretation. *See, e.g., Warner-Lamabert Co. v. Heckler*, 787 F. 2d 147 (3d Cir. 1986).

96. However, in selected situations, where supported by the available science and data, the FDA applied this framework in a flexible manner by approving NDAs or sNDAs based on a single adequate and well-controlled study, supported by pertinent information from other adequate and well-controlled studies.

97. In 1997, Congress provided explicit authority for this approach by enacting the FDA Modernization Act of 1997 ("FDAMA"; P.L. 105-115). Section 115(a) of FDAMA amended the FD&C Act to provide explicit authority for the FDA to consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" as constituting "substantial evidence." 21 U.S.C. §355(d).

98. Section 119(a) of the FDAMA amended §505(b) of the FD&C Act and directed the FDA to meet with sponsors who request to meet, provided certain conditions are met, to reach agreement on the design and size of the well-controlled clinical trials intended to form the primary basis for a demonstration of effectiveness in a marketing application submitted under §505(b) of the FD&C Act or §351 of the Public Health Service Act (42 U.S.C. §262).

99. As set forth in the current Special Protocol Assessment ("SPA") provisions in §505(b)(5)(B) and (C) of the FD&C Act:

> [I]f a sponsor makes a reasonable written request to meet with FDA to reach agreement on the design and size of a trial covered by the statute, FDA will grant the request. ***If FDA and the sponsor reach an agreement, FDA will put the agreement in writing and make it part of the administrative record*** (see the User Fee Acts section in this Appendix for a discussion of FDA's performance goals for review). ***Neither FDA nor the sponsor may change an agreement after the trial begins*** except: (1) with the written consent of the sponsor; or (2) if the FDA division director determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun." ***Should it be necessary for FDA to change or rescind an SPA agreement, FDA will first give the sponsor the opportunity for a meeting*** at which the FDA division director will be present and at which the director will document the scientific issue involved.

[Emphasis added].

100. Here, no such writing reflecting an agreement between the FDA and Acadia that provides for approval based on results for the overall DRP population enrolled in the Harmony Study, and not subpopulations, exists. To be sure, had it existed, Acadia would have undoubtedly published the agreement, rather than reference in general terms what is supposedly captured within it.

101. Moreover, there is nothing suggesting that the FDA offered Acadia an opportunity to meet to discuss the scientific issues involved in the sNDA. To the contrary, when Acadia was advised of the deficiencies in its application, it "immediately and repeatedly" reached out to the FDA for additional details, but "received nothing" in response.

102. And, finally, the FDA's history of issuing SPAs supports a finding that it is highly unlikely that the FDA *sua sponte* rescinded or changed its course. Since the FDAMA was enacted through 2016, the FDA has issued more than 1,000 SPA agreements and ***less than 1 percent of those SPAs*** have been rescinded. [Emphasis added].

103. Consequently, in light of what happened, and based on the foregoing, it is quite implausible that a written or oral agreement existed between the FDA and Acadia. And, even if there was a general agreement that the Company could do a single adequate and well-controlled study, that agreement was obviously contingent on the data being supportive of the subgroups that Acadia sought to treat with pimavanserin, and that was most certainly not the case.

D. Defendants' Monetized the Fraud Through Large Stock Sales

104. On or about September 17, 2019, Acadia raised net proceeds of approximately $271.5 million in a follow-on public offering. In the offering, the Company sold 7,187,500 shares of Acadia common stock, including 937,500 shares

sold pursuant to the exercise in full of the underwriters' option to purchase additional shares, at a price of $40 per share, for gross proceeds of $287.5 million.

105. Defendant Davis sold $24,771,568 worth of Acadia stock during the Class Period, or 541,205 shares. Much of Davis's sales during the Class Period were pursuant to Rule 10b5-1 trading plans that were adopted by Davis during or just before the Class Period; specifically, on August 22, 2019, and December 19, 2019. Since the end of the Class Period, Davis has sold just $211,176 worth of Acadia stock or 10,813 shares. Prior the Class Period, Davis had sold no Acadia stock.

106. Defendant Stankovic sold $18,932,729 worth of Acadia stock during the Class Period, or 368,993 shares. Much of Stankovic's sales during the Class Period were pursuant to Rule 10b5-1 trading plans that were adopted by Stankovic during the Class Period; specifically, on November 8, 2019, and December 3, 2020. Since the end of the Class Period, Stankovic has sold just $162,576 worth of Acadia stock or 8,371 shares. Prior the Class Period, Stankovic had sold no Acadia stock.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

107. The Class Period begins on September 9, 2019. On that day, Acadia issued a press release stating:

> ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced that its Phase 3 HARMONY study, a double-blind, placebo-controlled relapse prevention trial evaluating pimavanserin for the treatment of dementia-related psychosis, met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis.
>
> . . .
>
> The Company is planning to meet with the FDA regarding a supplemental NDA submission in 2020 and the results from the HARMONY study will be submitted for presentation at upcoming medical meetings.
>
> . . .
>
> "We are very excited that today's results bring us one step closer to the potential of offering patients with dementia-related psychosis a

> critically needed treatment option," said Serge Stankovic, M.D., M.S.P.H., ACADIA's President. "We look forward to speaking with the FDA about a supplemental new drug application to support pimavanserin for the treatment of dementia-related psychosis. I want to thank all of the patients, their families, and the investigators for their participation in this important study."

108. The foregoing was false and misleading because it failed to disclose that, due to a very small sample size of patients in each subgroup, the Harmony Study could not effectively determine whether pimavanserin was an effective treatment for the different subgroups. Therefore, undisclosed by Defendants, FDA approval was extremely unlikely unless the results from the Harmony Study were very strong. In fact, the data was disappointing, particularly as to the non-Parkinson's patients, indicating that the likelihood of approval was very low.

109. During a conference call held on September 9, 2019, to discuss the Harmony Study results, Defendant Stankovic represented:

> As Steve mentioned, pimavanserin was previously granted Breakthrough Therapy Designation for dementia-related psychosis. This was based on the seriousness of the disease with unmet need and the clinical results we have already observed, including our positive Alzheimer's disease psychosis study, which showed statistically significant reduction in psychotic symptoms in patients with Alzheimer's disease versus placebo without a negative impact on measure of cognitive function. And our positive Phase III pivotal study showing improvement in severity and frequency of hallucinations and delusions in patients with Parkinson's disease psychosis. This study included a prespecified subgroup analysis of dementia patients who, when treated with pimavanserin, also showed a statistically significant improvement in psychosis compared to placebo.
>
> ***I would also like to remind you that at the end of Phase II meeting with FDA, we confirmed that for our supplemental NDA submission in DRP, we could rely on a single, well-controlled study whose results were both statistically and clinically very persuasive.***
>
> In addition to the pivotal HARMONY study, we plan to submit in the supplemental NDA positive data in patients with dementia from the 2 previous efficacy studies as well as additional safety data from our ongoing placebo-controlled post-marketing commitment safety study of pimavanserin in elderly frail patients with neuropsychiatric symptoms related to neurodegenerative disease.
>
> [Emphasis added].

110. The foregoing was false and misleading because it failed to disclose that, due to a very small sample size of patients in each subgroup, the Harmony Study could not effectively determine whether pimavanserin was an effective treatment for the different subgroups. Therefore, undisclosed by Defendants, FDA approval was extremely unlikely unless the results from the Harmony Study were very strong. In fact, the data was disappointing, particularly as to the non-Parkinson's patients, indicating that the likelihood of approval was very low. Moreover, the assertion that the FDA had blessed Acadia's approach to the sNDA was false because no such agreement was reached.

111. During an October 30, 2019 earnings call to discuss the Company's financial results for the third quarter of 2019, the following colloquy between a research analyst and the Individual Defendants occurred:

> **Tazeen Ahmad BofA Merrill Lynch, Research Division – VP**
>
> This is either for Serge or for Steve. We're looking forward to seeing your data set presented at CTAD on the 4th of December. And ahead of that, I'm just wondering if you could give us an idea, of what additional details from the study you plan on showing? So should we expect to see a breakout of the different subsets of patients that were studied as part of the DRP indication? And I guess related to that, is your expectation that you would get a label just simply saying DRP? Or would it be specific to maybe the subgroups that seem to be most responsive, if there were subgroups that were more responsive than others?
>
> **Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director**
>
> Great. Thanks for the question, Tazeen. It's a 2-part question, Serge, and we're going to let you take both of them.
>
> **Srdjan R. Stankovic ACADIA Pharmaceuticals Inc. – President**
>
> Yes, sure. Let me first tackle the -- what data we will plan to present at CTAD. We will be sharing all material top line results from the study, meaning efficacy data from the open-label portion of the trial, primary and key secondary endpoint details in the trial, particularly obviously, in the randomized withdrawal portion, as well as overall safety data. So as part of that to -- specifically to your question, we will be presenting the data related to different subtypes of dementia as well.

> To your second question, all discussions that we had with the FDA and our initial intention were related to us pursuing indication of the treatment of hallucinations and delusions in dementia-related psychosis. So yes, indeed, that is what we are pursuing, and that is what we had discussed with the FDA.

112. The foregoing was false and misleading because the assertion that the FDA agreed with Acadia's approach was false. Further, Stankovic misleadingly failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

113. During the February 26, 2020 earnings call to discuss the Company's financial results for the fourth quarter of 2019 and fiscal year 2019, the following colloquy occurred between research analysts and the Individual Defendants:

> **Srdjan R. Stankovic ACADIA Pharmaceuticals Inc. – President**
>
> Yes. Ritu, we have all of the data that will constitute our supplemental NDA. The pivotal HARMONY study results will be the basis of the sNDA submission, which was previously agreed upon at the end of Phase II meeting. And in addition, we will have supportive efficacy results from our previous short-term studies, which provided evidence of acute efficacy of pimavanserin in Alzheimer's disease and in Parkinson's disease psychosis for patients -- with patients with dementia. And finally, we plan to submit our extensive safety data from completed and ongoing studies. So what is left for us is to essentially put that all together in the format required for the supplemental NDA, all the study reports and summary documents and once we agree with FDA on that, to submit.
>
> **Ritu Subhalaksmi Baral Cowen and Company, LLC, Research Division – MD & Senior Biotechnology Analyst**
>
> And so you've generated all the safety data and safety analysis used for that NDA -- sNDA, sorry.
>
> **Srdjan R. Stankovic ACADIA Pharmaceuticals Inc. – President**
>
> Yes. We generated all the -- both efficacy and safety data that we will be submitting with that supplemental NDA.
>
> . . .
>
> **Alexander Thompson Stifel, Nicolaus & Company, Incorporated, Research Division – Research Analyst**

> This is Alex on for Paul. Just a quick question on your upcoming sNDA meeting. Just wondering if you could sort of give us a sense of what your goals are for the meeting, what you expect to discuss with the FDA just generally? And if you'll provide us with an update once that's occurred? Great.
>
> . . .
>
> **Srdjan R. Stankovic ACADIA Pharmaceuticals Inc. – President**
>
> Yes, happy to. As I mentioned earlier, we are meeting with the FDA primarily to review the content and format of our application, meaning we will be discussing with the totality of the data. We are bringing both efficacy and safety data. We are bringing to the sNDA as well as the different ways of analysis and pooling of the data in order to present better and enable reviewers to do their review both on the efficacy and the safety side. So discussing then that content and the format of that data presentation is -- are our main objectives in the discussion with the FDA.

114. The foregoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

115. On May 7, 2020, Defendant Stankovic stated the following during the Company's earnings call for the first quarter of 2020:

> As planned, we successfully completed a pre-sNDA meeting with the FDA and confirm that the pivotal data from our HARMONY study, together with the confirmatory and supportive results from our Alzheimer's disease psychosis Phase II study and our Parkinson's disease psychosis Phase III study will all support the submission of an sNDA for pimavanserin in dementia-related psychosis. In addition, we discussed the overall safety database and analysis plan. Our sNDA preparation remains firmly on track. As previously announced, we plan to submit the sNDA this summer. We expect a priority review with a potential approval for DRP around year-end.

116. The foregoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

117. On May 12, 2020, during the Bank of America Merrill Lynch Healthcare Conference, the following colloquy occurred between a research analyst and Defendant Davis:

> **Tazeen Ahmad BofA Merrill Lynch, Research Division – VP**
>
> I think I was on mute. Okay. Thanks for calling that out. So maybe we can talk a little bit about DRP, Steve, as one of your next indications. Can you review what you discussed with the FDA perhaps at the pre-sNDA meeting? Can you provide a little bit of expectations on time lines for submission and approval? I know you've talked about this in general and whether or not you still expect to have an AdCom, if you believe that there will be any kind of modifications of the current box warning?
>
> **Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director**
>
> Yes, absolutely. So as I mentioned, we had our pre-sNDA meeting in the first quarter. The feedback there was very consistent with what we heard with our end-of-Phase II meeting. The FDA confirmed that the studies conducted can support an sNDA submission with HARMONY as the pivotal study, and our Phase II Alzheimer's disease study and Phase III Parkinson's disease psychosis study as supportive efficacy studies.

118. The foregoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval. Furthermore, the assertion that the FDA had "confirmed" that Acadia's approach could support the sNDA was false. Again, the FDA's actions are inconsisent with the provision of any written or oral commitment to Acadia regarding the validity of its approach.

119. On June 15, 2020, Acadia issued a press release announcing the submission of the pimavanserin sNDA, stating, in relevant part:

> SAN DIEGO--(BUSINESS WIRE)--ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) announced today that the company submitted a [sNDA] to the [FDA] to support a potential new indication for NUPLAZID® (pimavanserin) for the treatment of hallucinations and delusions associated with dementia-related psychosis (DRP). The FDA previously granted Breakthrough Therapy Designation for

> pimavanserin for the treatment of hallucinations and delusions associated with DRP.
>
> "This is an important step forward for the approximately 2.4 million people in the U.S. who suffer from dementia-related hallucinations and delusions, representing a large unmet need with currently no approved treatment options," said Steve Davis, ACADIA's Chief Executive Officer. "Our pivotal HARMONY study showed a meaningful reduction of the symptoms and stabilization of psychosis and a nearly three-fold reduction in the risk of relapse of psychosis for patients continuing treatment on pimavanserin compared to placebo. We look forward to working with the FDA as it reviews our submission."
> The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023). The sNDA also includes positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: The Phase 2 (-019) study in patients with Alzheimer's disease psychosis and the Phase 3 (-020) study in patients with Parkinson's disease psychosis. The sNDA includes a large safety and tolerability database from completed and ongoing studies representing over 1500 patients with neurodegenerative disease.

120. The foregoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

121. On July 20, 2020, Acadia issued a press release announcing that the FDA had accepted the pimavanserin sNDA for filing. The press release stated, in relevant part:

> "We are pleased that the FDA has accepted our sNDA for filing and we will be working closely with the FDA to facilitate completion of the review in a timely manner," said Steve Davis, ACADIA's Chief Executive Officer. "If approved, NUPLAZID would be the first therapy indicated for the treatment of hallucinations and delusions associated with dementia-related psychosis. We look forward to potentially bringing this important treatment advancement to patients, caregivers and physicians."

122. The forgoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

123. On August 5, 2020, Acadia issued a press release announcing the Company's second quarter 2020 financial results. The press release stated, in relevant part:

> "In the first half of 2020 we drove robust growth of NUPLAZID®. With the FDA filing of our sNDA for dementia-related psychosis we are one step closer to potentially delivering the first and only approved treatment for this devastating condition," said Steve Davis, ACADIA's Chief Executive Officer. "Building upon the successful development of our PDP and DRP programs, our clinical team is focused on advancing our innovative early- and late-stage pipeline."

124. The foregoing was false and misleading because Defendants failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval.

125. On August 19, 2020, at the JMP Securities CNS Forum, the following colloquy occurred between a research analyst and the Individual Defendants:

> ***Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director***
>
> I'll just -- just to echo Michael's thoughts, one of the things we hear very consistently among KOLs, just physicians generally is the -- and as we've said before, the "subtypes" of dementia are very difficult to diagnose. They overlap many times. And so it's a little bit of an artificial distinction to say someone has Alzheimers, dementia with Lewy bodies or vascular dementia, et cetera.
>
> And so -- and one of the advantages, of course, pursuing dementia-related psychosis broadly, which is just, as a reminder, we got a clear agreement from -- with the FDA at our end of Phase II meeting, and we executed the plan that we agreed to with them. One of the advantage is it picks up what's referred to as dementia not otherwise specified, that's coded as not otherwise specified. And that's a big chunk of patients. And that -- the fact that so many patients are not specified other than beyond just saying dementia, is again, a reflection of the fact that these categories are very difficult to diagnose. So as Michael mentioned, the good news is physicians understand that. They operate in that world. And with the indication that we are seeking, it won't matter. They won't have to try to make a determination, whether it's Alzheimer's or vascular dementia or something else.
>
> **Jason Nicholas Butler JMP Securities LLC, Research Division – MD, Director of Healthcare Research & Equity Research Analyst**

> And that's a really good point. And so let me just ask one more question about the FDA there. You obviously have this very broad patient population under the DRP umbrella. How do you think about more broadly the label indication statement based on the Phase III trial design, specifically the relapse prevention relative to PDP, where you had an initiation kind of trial design?
>
> **Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director**
>
> Yes. Well, let me take it in from 2 perspectives. Let me take it from a regulatory perspective and then from a medical perspective. From a regulatory perspective, I just want to remind everyone that the sNDA that we've submitted includes the HARMONY study, the relapse prevention study but also includes -- or the kind of study that we did in Parkinson's disease psychosis. It includes acute -- we'll call it acute data as well over a much shorter time frame and it showed positive results, both in an Alzheimer's population as well as our -- of course, our Parkinson's disease psychosis population. So we have both in the submission.
>
> More importantly, we agreed with the FDA on that approach at our end of Phase II meeting and agreed on the plan for Phase III, and then we've executed that plan. From a medical perspective, it's also important because physicians -- and they think -- again, when they think about dementia-related psychosis, they oftentimes just think about it more broadly speaking. As they think about a relapse prevention study, what we hear over and over is it really resonates with them.
>
> Many times in neuropsychiatry, when you get approval on a drug, it's based upon -- we ran 1 arm with drug, 1 arm with placebo. We measured them on -- we measured progress on the scale. We compared those 2 and have indication of efficacy. But physicians don't do that in practice. They don't use those scales, and they're really just looking at the clinical manifestation of the disease in the patient that they're seeing in the examining room on. And they're thinking about things like will this impact their symptoms, and if so, will it have a durability of effect. So the relapse prevention study really resonates with the medical community because it aligns with a clinical outcome and the kinds of things that they think about.

126. The foregoing were false and misleading because Defendants failed to disclose that known shortcomings the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval. Furthormore, the representation that the FDA had "agreed" with Acadia and that Acaida had "executed" an agreed to "plan" was false. The FDA's actions in rejecting Acadia's sNDA are inconsisent with any argreement with Acadia.

127. On August 6, 2020, Acadia 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"). The 2Q20 10-Q touted the pimavanserin sNDA, stating, in relevant part:

> [W]e believe dementia-related psychosis (DRP), represents one of our most important opportunities for further exploration. In June 2020, we submitted a [sNDA] for NUPLAZID for the treatment of hallucinations and delusions associated with DRP. In July 2020 the FDA notified us of acceptance of our sNDA with a PDUFA date of April 3, 2021. The FDA advised us that it has not identified any potential review issues at this point in their evaluation and at this time they are not planning to hold an Advisory Committee meeting. The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023). The sNDA also includes positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: the Phase 2 (-019) study in patients with Alzheimer's disease psychosis and the Phase 3 (-020) study in patients with Parkinson's disease psychosis. The sNDA includes a large safety database from completed and ongoing studies representing over 1,500 patients with neurodegenerative disease. An estimated 8.0 million people in the United States are living with dementia, and studies suggest that approximately 30% of dementia patients, or 2.4 million people, have psychosis, commonly consisting of delusions and hallucinations. Approximately 1.2 million patients in the United States are currently treated for DRP and, of those treated, approximately two-thirds are treated with off-label anti-psychotics. In the fourth quarter of 2017, the FDA granted Breakthrough Therapy Designation for pimavanserin for the treatment of DRP.

128. On September 14, 2020, during a healthcare conference, the following colloquy occurred between a research analyst and the Individual Defendants:

> **Jeff Hung Morgan Stanley, Research Division – Equity Analyst**
>
> And what is your view on the recent string of complete response letters? Is there any reason to believe that there are any changes at the agency that might add risk to approval in DRP?
>
> **Srdjan R. Stankovic ACADIA Pharmaceuticals Inc. – President**
>
> Well, I would say that we generally avoid to comment on other applications because we are not familiar with the details of the review or details of the data and all that. We do not see -- each situation is different, and we do not see any particular policy arising from that attitude from these decisions, the different decision made. It may have

to do with the timing, with resources, ability to be able to complete those things and asking for additional data. We continue to be very confident, as I said, in our data. It's very consistent with what we've been finding as we have been adding the new information, both in terms of efficacy and safety. We have a strong package and are currently focusing on facilitating review toward approval.

. . .

Jeff Hung Morgan Stanley, Research Division – Equity Analyst

Okay. And then multiple neurodegenerative disorders have patients with dementia-related psychosis, such as Alzheimer's. Which disorders do you think are more likely to have faster adoption? Do you think there will be certain ones that contribute more early on in the launch? And then, I guess, on the other hand, what kinds of things do you need to work on for the disorders that may not ramp up as quickly or early on in the launch such as patient or physician education?

Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director

Yes. Let me take just a little bit of running start at it. So in dementia-related psychosis, sometimes people think about various subtypes. And of course, we've talked about that as well. But just one, just as a background reminder that we received agreement with the FDA that we would pursue dementia-related psychosis broadly in order to treat the symptoms of psychosis, regardless of their clinically diagnosed subtype. And I just want to be clear here, that subtype diagnosis is very subjective. It's difficult to diagnose. Many times, physicians don't know what the underlying etiology is as you sometimes going to only find it out through autopsy.

129. The foregoing statements were false and misleading because Defendants failed to disclose that, due to a very small sample size of patients in each subgroup, the Harmony Study could not effectively determine whether pimavanserin was an effective treatment for the different subgroups. Therefore, undisclosed by Defendants, FDA approval was extremely unlikely unless the results from the Harmony Study were very strong. In fact, the data was disappointing, particularly as to the non-Parkinson's patients, indicating that the likelihood of approval was

very low. Moreover, the assertion that the FDA had blessed Acadia's approach to the sNDA was false because no such agreement was reached.

130. On November 4, 2020, Acadia hosted an earnings call with investors and analysts to discuss the Company's third quarter 2020 results (the "3Q20 Earnings Call"). During the scripted portion of the 3Q20 Earnings Call, Defendant Davis stated, in relevant part:

> We are well-prepared to achieve the long-term market opportunity for NUPLAZID in PDP and look forward to the addition of the DRP indication.
>
> . . .
>
> We are excited that pimavanserin could be the first and only FDA approved medicine for the treatment of dementia-related psychosis.
>
> . . .
>
> We are confident in both the efficacy and safety data supporting our supplemental NDA and we will continue to work with the FDA to facilitate their review with a PDUFA date of April 3, 2021.
>
> We continue to make important progress in our late stage development pipeline as shown on Slide 8, with but ongoing Phase 3 studies with pimavanserin for the treatment of negative symptoms of schizophrenia and with trofinetide for the treatment of Rett Syndrome.

131. The foregoing was false and misleading because Defendants failed to disclose that, due to a very small sample size of patients in each subgroup, the Harmony Study could not effectively determine whether pimavanserin was an effective treatment for the different subgroups. Therefore, undisclosed by Defendants, FDA approval was extremely unlikely unless the results from the Harmony Study were very strong. In fact, the data was disappointing, particularly as to the non-Parkinson's patients, indicating that the likelihood of approval was very low.

132. At a November 17, 2020 healthcare conference, the following colloquy occurred between the Individual Defendants and an analyst:

Paul Andrew Matteis Stifel, Nicolaus & Company, Incorporated, Research Division – Co-Head of the Biotech Team, MD & Senior Analyst

I guess as you've had continued engagement with the FDA, is there any interpretation you have on the lack of priority review? Investors and analysts love to read these tea leaves. And I've been misled by priority review and no panel, resulting in a CRL. So I won't overdo it, but what did you think internally then? And how do you guys feel about the intent?

Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director

Yes. Thanks much for the question. So let me just start by saying we remain highly confident in both the efficacy and safety data supporting our submission. And of course, at this point, we're focused on facilitating the FDA's review, which, as I mentioned, remains on track. And just as a brief reminder, our sNDA submission included an efficacy package, which was agreed upon with the FDA at the end of Phase II meetings before we conducted the pivotal HARMONY study. And based upon the robust and meaningful results from HARMONY and the additional supporting data from other efficacy studies in Alzheimer's and Parkinson's patients, and then just the overall safety profile of pimavanserin, we remain very confident in the potential approval for DRP.

So again, just as I put it -- with that backdrop, at our end of Phase II meeting, we went to the FDA. We said we think we have demonstrated sufficient efficacy in acute setting. We'd like you to agree to 3 things: one, that we studied DRP generally. They agreed to that. That was actually a very short discussion. Two, that we run a relapse-prevention study now to demonstrate the -- not only that we can stabilize patient symptoms, but that we get a durable effect over time. And then three, that we -- that a single relapse prevention study serve as the basis of approval, together with the other supporting acute studies we've done. And they've agreed to all 3 of those. That's documented in our minutes. So fast forward to today, we then executed the exact plan that we laid out for them. And again, that underlines the confidence we have in the potential for approval in DRP.

Paul Andrew Matteis Stifel, Nicolaus & Company, Incorporated, Research Division – Co-Head of the Biotech Team, MD & Senior Analyst

Got it. Okay. Great, Steve. What were your discussions with the FDA and what you need to show for safety? I mean, there's this whole -- we had Alzheimer's panel here at this conference yesterday and one of the panelists walked through the whole back history, going back to the

2000s with atypicals in the elderly and the original black box and changes in policy and things like that. What did FDA -- did they ever articulate to you what they wanted to see, right? It's obviously very hard to disprove a negative. And I guess, were they going to rely more on just your DRP clinical data? Or how much of the PDP post-marketing data goes into this?

Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director

Yes. They're both important. One thing that I didn't mention is that in the Phase II meeting we had setting up our Phase III program that we then executed, is in addition to those 3 points, we also just asked FDA very specifically. We said we just want to make certain that you are on board with approving a drug to treat dementia-related psychosis. Because today, there's a class warning for all antipsychotics, basically contraindicating that patient population. We want to make certain that you are on board with the concept of doing this if we followed the plan that we've agreed to.

And they said, absolutely, we wouldn't agree to your Phase III plan if we weren't in that -- if we weren't of that mind. So again, fast forward to today, we've been on the market for 4 years. We've continued to run placebo controlled studies. If you look at the totality of the data that we have today on -- just on safety, if anything, the safety profile and tolerability profile of the drug looks even better than it did when we got our PDP approval.

Most recently, or as a component of that PDP approval, we agreed to a post-marketing commitment to run a substantial number of patients in placebo-controlled study for elderly patients, evaluating them over -- against placebo over a period of at least 8 weeks. And we -- that commitment is due to be completed in the next year or 2. But any time you file an sNDA, you need to collect all the safety data that you've generated since your prior NDA approval. We've done that, including the most recent cut from that safety study. And like I said before, every cut of data that we've had continues to support, if not look even better than the original basis for approval in PDP. So we've submitted that data and that all looks very consistent with what we know about the drug.

Paul Andrew Matteis Stifel, Nicolaus & Company, Incorporated, Research Division – Co-Head of the Biotech Team, MD & Senior Analyst

Got it. That's great. All right. Last here of the regulatory question, I promise, because I don't want to belabor it. Between the PDUFA, Steve, are there any 3 like inflection points during the review from your seat that can be articulated and continue to convey comfort to investors?

Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director

> We're following the same path that we did in the PDP review and that most companies do when they're in registration, that is, we're not going to comment on the specific back and forth that we're having with FDA. I just don't think that will be productive. But what I will say is, we remain on track. We remain just as confident as we've ever been in the potential for approval and just eager to get to the PDUFA date.

133. The foregoing was false and misleading because Defendants failed to disclose that the Harmony Study was not properly designed to evaluate the efficacy of pimvanserin and that the data supporting the sNDA was disappointing and not strong enough to support approval. Also, the assertion that the FDA agreed with Acadia on its approach was false.

134. During a January 12, 2021 presentation at a healthcare conference, Defendant Davis made the following statement:

> Pimavanserin has the potential to be the first treatment approved for DRP, and I'm pleased to report that our sNDA submission is progressing well and as we would expect at this point in the review cycle. Pimavanserin selective serotonergic mechanism is highly differentiated. It's unlike any other antipsychotic on the market. And as I mentioned, the DRP market opportunity is very large, and approximately two thirds of the 1.2 million patients treated for DRP today are treated with off-label atypical antipsychotics, which, as I mentioned, carry significant disease burden or side effect burden. Our sNDA is supported by strong and robust efficacy data. Pimavanserin demonstrated an almost three-fold reduction in risk of relapse of psychosis in our pivotal HARMONY study. Our sNDA also includes positive results from 2 supportive efficacy studies, a positive Phase II study in Alzheimer's Disease psychosis; and positive data from our pivotal Phase III study in Parkinson's disease psychosis in patients with dementia. Our sNDA is also supported by strong safety data. Pimavanserin is well tolerated and notably exhibited no worsening of cognition, no worsening of motor function and no increase in sedation. As we prepare for the DRP launch, we are well positioned to leverage our established capabilities and expertise.

135. Also during the January 12, 2021 conference, Defendant Davis had the following colloquy with an analyst:

Cory William Kasimov JPMorgan Chase & Co, Research Division – Senior Biotechnology Analyst

> … obviously, everybody is really focused, as I'm sure you are, on your pending PDUFA date for NUPLAZID for DRP. Can you just kind of frame expectations for what you would maybe expect or hope a label would look like, and the importance that will play in the commercialization of the product for the indication?

Stephen R. Davis ACADIA Pharmaceuticals Inc. – CEO & Director

> Yes. Thanks much, Cory. I'll start and then -- and Serge may want to add some additional color as well. So the indication we'll be seeking is as NUPLAZID is indicated for the treatment of dementia-related psychosis. And there are probably 2 key elements that we should touch on here: One is the -- as I mentioned, we're seeking the treatment of dementia-related psychosis. So we're not looking at individual subtypes as they are often referred to of dementia. The psychosis that we see is very similar between the -- irrespective of the underlying etiology and it responds in a similar way. So we're seeking that broad indication. That's supported by a very both alignment we established with the FDA at our end of Phase II meeting and then again at their pre-sNDA meeting when we submitted our application. The efficacy and safety data that we have, that underpins that indication, is very strong. We've got a well-established, safety and tolerability profile of the drug. Any time you file an sNDA, you need to collect all of the safety data you have from either prior or ongoing studies we've done that, all of that data continues to look very positive. If anything, the profile of the drug might look even a little bit cleaner than the very, very clean profile that we observed when we submitted in PDP.

136. The foregoing was false and misleading because Defendants failed to disclose that the Harmony Study was not properly designed to evaluate the efficacy of pimvanserin and that the data supporting the sNDA was disappointing and not strong enough to support approval. Also, the assertion that the FDA agreed with Acadia on its approach was false.

137. On February 24, 2021, Acadia issued a press release announcing the Company's fourth quarter and full year 2020 financial results. The press release stated, in relevant part:

> "Acadia delivered strong financial results in the fourth quarter and full year 2020, driven by robust sales of NUPLAZID in Parkinson's disease psychosis. Additionally, we made significant advancements in two Phase 3 programs and further expanded our pipeline in pain and neuropsychiatry through strategic business development," said Steve

> Davis, Chief Executive Officer. "In 2021, we are focused on delivering continued growth of NUPLAZID, the upcoming potential approval and launch of pimavanserin for dementia-related psychosis and advancing our business development strategy."

138. That same day, Acadia hosted an earnings call with investors and analysts to discuss the Company's fourth quarter and full year 2020 results (the "4Q20 Earnings Call"). During the scripted portion of the 4Q20 Earnings Call, Defendant Davis stated, in relevant part:

> Additional highlights from 2020 include our submission of an sNDA for DRP. The FDA review is progressing as expected, and we look forward to the potential NUPLAZID becoming the first and only approved treatment for this indication, and the first new treatment in the dementia space in over 15 years.
>
> * * *
>
> The significant potential of pimavanserin, combined with our clinical pipeline, will drive meaningful long-term growth. We continue to grow NUPLAZID sales, and based on our 2020 performance and current outlook, we are providing net sales guidance for PDP in fiscal year 2021 of $510 million to $550 million.
>
> We're on the cusp of a potential approval in DRP, a significantly larger market opportunity for which our teams have been preparing for approximately two years. We will be ready to execute on day 1. In addition, we're advancing our pipeline with clinical trials across five separate indications.

139. The foregoing was false and misleading because Acadia was not "on the cusp of potential approval in DRP." Acadia was well on its way to a predictable rejection based on the Harmony Study's poor design and the poor results submitted to support the sNDA, all of which were known to Defendants.

140. On February 25, 2021, Acadia 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"). The 2020 10-K stated, in relevant part:

> [W]e believe dementia-related psychosis (DRP), represents one of our most important opportunities for further development. In June 2020, we submitted to the FDA a supplemental New Drug Application (sNDA) for NUPLAZID for the treatment of hallucinations and delusions associated with DRP. In July 2020 the FDA notified us of their filing

> of our sNDA with a Prescription Drug User Fee Act (PDUFA) target action date of April 3, 2021.

141. In addition, in a section discussing company strategy, the 2020 10-K stated, in relevant part:

> Our strategy is to identify, develop and commercialize innovative therapies that address unmet medical needs in CNS disorders. Key elements of our strategy are to:
>
> . . .
>
> ***Deliver pimavanserin to the market for the treatment of patients with dementia-related psychosis***. In June 2020, we submitted an sNDA for NUPLAZID for the treatment of hallucinations and delusions associated with DRP. Our PDUFA target action date is April 3, 2021. In preparation for a potential U.S. launch, we plan to increase the U.S. sales force, including expansion of additional commercial, medical affairs and general and administrative support functions prior to obtaining regulatory approval for NUPLAZID in DRP. If approved, NUPLAZID will be the first and only FDA-approved treatment for DRP.

[Emphasis added].

142. The foregoing was false and misleading because Defendants failed to disclose that the Harmony Study was not properly designed to evaluate the efficacy of pimvanserin and that the data supporting the sNDA was disappointing and not strong enough to support approval.

THE TRUTH BEGINS TO EMERGE

143. On March 8, 2021, post-market, Acadia issued a press release providing a regulatory update on the pimavanserin sNDA, disclosing "that the Company received a notification from the [FDA] on March 3, 2021, stating that, as part of its ongoing review of the Company's [sNDA], the FDA has identified deficiencies that preclude discussion of labeling and post- marketing requirements/commitments at this time." Acadia advised that "[t]he notification does not specify the deficiencies identified by the FDA and there has been no clarification by the FDA at this time."

144. On this news, Acadia's stock price fell $20.76 per share, or 45.35%, to close at $25.02 per share on March 9, 2021.

145. Then, on April 5, 2021, pre-market, Acadia issued a press release announcing that the Company had received a CRL from the FDA indicating that the pimavanserin sNDA could not be approved in its current form. Specifically, the press release stated, in relevant part:

> Despite prior agreements with the Division of Psychiatry regarding the pivotal Phase 3 HARMONY study design targeting a broad DRP patient population analyzed as a single group, the Division, in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval.
>
> The DRP pivotal HARMONY study met its prespecified primary and secondary endpoints with robust and persuasive clinical and statistical superiority of pimavanserin over placebo, which was a prospectively agreed prerequisite for the DRP indication. Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements. "Acadia stands behind the robustly positive results from the pivotal Phase 3 HARMONY study and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the Division did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL," said Steve Davis, Chief Executive Officer of Acadia. "We will immediately request a Type A meeting to work with the FDA to address the CRL and determine an expeditious path forward for the approval of pimavanserin in DRP."
>
> The Division also stated in the CRL that it considers the Phase 2 Alzheimer's disease psychosis study -019, a supportive study in the sNDA filing, to not be adequate and well controlled, citing that it was a single center study with no type I error control of secondary endpoints in which certain protocol deviations occurred. The Company believes these observations impact neither the positive results on the study's primary endpoint, nor the study's overall conclusions of efficacy. There were no safety issues or concerns raised in the CRL.

146. On this news, Acadia's stock price fell $4.41 per share, or 17.23%, to close at $21.18 per share on April 5, 2021.

147. 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

148. 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 Acadia common stock 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.

149. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Acadia common stock was 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 Acadia 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.

150. 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.

151. 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.

152. 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 Acadia;
- whether the Individual Defendants caused Acadia 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 price of Acadia common stock was inflated during the Class Period due to 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.

153. 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.

154. 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;
- Acadia common stock is 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 Acadia 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.

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

156. 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)

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

158. 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.

159. 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 Acadia common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Acadia common stock 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.

160. 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 Acadia common stock. 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 Acadia's finances and business prospects.

161. By virtue of their positions at Acadia, 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.

162. 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 Acadia, the Individual Defendants had knowledge of the details of Acadia's internal affairs.

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

164. During the Class Period, Acadia common stock was 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 Acadia 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 Acadia common stock was substantially lower than

the prices paid by Plaintiff and the other members of the Class. The market price of Acadia common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

165. 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.

166. 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)

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

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

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

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

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

172. 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 Acadia.

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: December 10, 2021

SCOTT+SCOTT ATTORNEYS AT LAW LLP

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CERTIFICATE OF SERVICE

I hereby certify that on December 10, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

s/ John T. Jasnoch
John T. Jasnoch