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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

Case No.: '18CV1647 BEN MDD

Similarly Situated,

Plaintiff,

v.

ACADIA PHARMACEUTICALS
INC., STEPHEN R. DAVIS, and
TODD S. YOUNG,

Defendants.

**CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE
FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

1 Plaintiff “Plaintiff”), by and through his attorneys, alleges
2 the following upon information and belief, except as to those allegations concerning
3 Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and
4 belief is based upon, among other things, his counsel’s investigation, which includes
5 without limitation: (a) review and analysis of regulatory filings made by ACADIA
6 Pharmaceuticals Inc. (“ACADIA” or the “Company”) with the United States
7 (“U.S.”) Securities and Exchange Commission (“SEC”); (b) review and analysis of
8 press releases and media reports issued by and disseminated by ACADIA; and (c)
9 review of other publicly available information concerning ACADIA.
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13 **NATURE OF THE ACTION AND OVERVIEW**

14 1. This is a class action on behalf of persons and entities that acquired
15 ACADIA securities between April 29, 2016 and July 9, 2018, inclusive (the “Class
16 Period”), seeking to pursue remedies under the Securities Exchange Act of 1934
17 (the “Exchange Act”).
18

19 2. ACADIA is purportedly a biopharmaceutical company focused on the
20 development and commercialization of medicines to address central nervous system
21 disorders. The Company claims its lead drug is NUPLAZID (pimavanserin), which
22 was approved by the U.S. Food and Drug Administration (“FDA”) on April 29,
23 2016 for the treatment of hallucinations and delusions associated with Parkinson’s
24 disease psychosis (or “PD Psychosis”). The Company launched NUPLAZID in the
25 United States in May 2016.
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1 3. On April 29, 2016, ACADIA issued a press release announcing that
2 that the FDA approved NUPLAZID for the treatment of hallucinations and
3 delusions associated with Parkinson’s disease psychosis. ACADIA further stated
4 that “[t]he FDA approval of NUPLAZID was based on data from the pivotal Phase
5 III Study -020 and other supportive studies, representing the largest research and
6 development program in Parkinson’s disease psychosis to date.”
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9 4. On February 27, 2018, ACADIA announced fourth quarter 2017
10 NUPLAZID sales of \$43.6 million, which was approximately \$720,000 below
11 consensus estimates.
12

13 5. On this news, ACADIA’s share price fell \$6.24 per share, or 20%, to
14 close at \$24.92 per share on February 28, 2018, on unusually heavy trading volume.
15

16 6. On April 9, 2018, CNN reported that “[p]hysicians, medical researchers
17 and other experts told CNN that they worried that [NUPLAZID] had been approved
18 too quickly, based on too little evidence that it was safe or effective. And given
19 these mounting reports of deaths, they say that more needs to be done to assess
20 Nuplazid’s true risks.”
21

22 7. On this news, ACADIA’s share price fell \$5.03 per share, or 23.4%, to
23 close at \$16.50 per share on April 9, 2018, on unusually heavy trading volume.
24

25 8. On April 25, 2018, CNN reported that the FDA was re-examining the
26 safety of NUPLAZID.
27

28 9. On this news, ACADIA’s share price fell \$4.27 per share, or 21.9%, to

1 close at \$15.20 per share on April 25, 2018, on unusually heavy trading volume.

2 10. On July 9, 2018, the Southern Investigative Reporting Foundation (the
3 “SIRF”) published a report entitled “Acadia Pharmaceuticals: This Is Not a
4 Pharmaceuticals Company.” Therein, the SIRF stated that “evidence is mounting
5 that something is horribly wrong with Acadia’s sole drug, Nuplazid, an
6 antipsychotic for Parkinson’s disease patients who experience episodic
7 hallucinations and delusions” and that “Acadia has accomplished its growth in ways
8 that have attracted intense regulatory scrutiny for other drug companies” including
9 “dispensing wads of cash to doctors to incentivize prescription writing and
10 downplaying mounting reports of patient deaths.”
11

12 11. On this news, ACADIA’s share price fell \$1.21 per share, or 6.8%, to
13 close at \$16.63 per share on July 9, 2018, on unusually heavy trading volume.
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15 12. Throughout the Class Period, Defendants made materially false and/or
16 misleading statements, as well as failed to disclose material adverse facts about the
17 Company’s business, operations, and prospects. Specifically, Defendants failed to
18 disclose: (1) that adverse events and safety concerns related to NUPLAZID
19 threatened the drug’s initial and continuing FDA approval; (2) that ACADIA
20 engaged in business practices likely to attract regulatory scrutiny; and (3) that, as a
21 result of the foregoing, Defendants’ statements about ACADIA’s business,
22 operations, and prospects, were materially false and/or misleading and/or lacked a
23 reasonable basis.
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1 13. As a result of Defendants' wrongful acts and omissions, and the
2 precipitous decline in the market value of the Company's securities, Plaintiff and
3 other Class members have suffered significant losses and damages.
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5 **JURISDICTION AND VENUE**

6 14. The claims asserted herein arise under Sections 10(b) and 20(a) of the
7 Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated
8 thereunder by the SEC (17 C.F.R. § 240.10b-5).
9

10 15. This Court has jurisdiction over the subject matter of this action
11 pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. §
12 78aa).
13

14 16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §
15 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts
16 in furtherance of the alleged fraud or the effects of the fraud have occurred in this
17 Judicial District. Many of the acts charged herein, including the dissemination of
18 materially false and/or misleading information, occurred in substantial part in this
19 Judicial District. In addition, the Company's principal executive offices are in this
20 Judicial District.
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24 17. In connection with the acts, transactions, and conduct alleged herein,
25 Defendants directly and indirectly used the means and instrumentalities of interstate
26 commerce, including the United States mail, interstate telephone communications,
27 and the facilities of a national securities exchange.
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PARTIES

18. Plaintiff as set forth in the accompanying certification, incorporated by reference herein, purchased ACADIA securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

19. Defendant ACADIA Pharmaceuticals Inc. is incorporated in Delaware and its principal executive offices are in San Diego, California. ACADIA’s common stock trades on the NASDAQ Stock Market (“NASDAQ”) under the symbol “ACAD.”

20. Defendant Stephen R. Davis (“Davis”) was the President and Chief Executive Officer (“CEO”) of ACADIA at all relevant times.

21. Defendant Todd S. Young (“Young”) was the Chief Financial Officer (“CFO”) of ACADIA from August 22, 2016, through the end of the Class Period.

22. Defendants Davis and Young (collectively the “Individual Defendants”), because of their positions with the Company, possessed the power and authority to control the contents of ACADIA’s reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company’s reports 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 cause them to be corrected. Because of their

1 positions and access to material non-public information available to them, the
2 Individual Defendants knew that the adverse facts specified herein had not been
3 disclosed to, and were being concealed from, the public, and that the positive
4 representations which were being made were then materially false and/or
5 misleading. The Individual Defendants are liable for the false statements pleaded
6 herein.
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9 **SUBSTANTIVE ALLEGATIONS**

10 **Background**

11 23. ACADIA is purportedly a biopharmaceutical company focused on the
12 development and commercialization of medicines to address central nervous system
13 disorders. The Company claims its lead drug is NUPLAZID (pimavanserin), which
14 was approved by the FDA on April 29, 2016 for the treatment of hallucinations and
15 delusions associated with PD Psychosis. The Company launched NUPLAZID in the
16 United States in May 2016.
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19 **Materially False and Misleading** 20 **Statements Issued During the Class Period**

21 24. The Class Period begins on April 29, 2016. On that day, the Company
22 issued a press release entitled “FDA Approves ACADIA Pharmaceuticals’
23 NUPLAZID™ (pimavanserin) - The First Drug Approved for the Treatment of
24 Hallucinations and Delusions Associated with Parkinson’s Disease Psychosis.”
25 Therein, the Company, in relevant part, stated:
26

27 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
28 biopharmaceutical company focused on the development and
commercialization of innovative medicines to address unmet medical

1 needs in central nervous system (CNS) disorders, today announced that
2 the U.S. Food and Drug Administration (FDA) has approved
3 NUPLAZID (pimavanserin) for the treatment of hallucinations and
4 delusions associated with Parkinson's disease psychosis. In 2014,
5 the FDA designated NUPLAZID as a Breakthrough Therapy for this
6 condition.

7 * * *

8 The FDA approval of NUPLAZID was based on data from the pivotal
9 Phase III Study -020 and other supportive studies, representing the
10 largest research and development program in Parkinson's disease
11 psychosis to date. In Study -020, NUPLAZID significantly reduced the
12 frequency and severity of psychotic symptoms compared to placebo on
13 the Scale for Assessment of Positive Symptoms – Parkinson's Disease
14 (SAPS-PD). This benefit was achieved without impairing motor
15 function. The most common adverse reactions ($\geq 5\%$ and twice the rate
16 of placebo) in this study were peripheral edema (7% NUPLAZID vs
17 3% placebo) and confusional state (6% NUPLAZID vs 3% placebo).
18 Results of Study -020 were published in The Lancet. Please see full
19 prescribing information at www.nuplazid.com.

20 25. On May 31, 2016, ACADIA issued a press release entitled "ACADIA
21 Pharmaceuticals Announces NUPLAZID™ (pimavanserin) Is Now Available for
22 the Treatment of Hallucinations and Delusions Associated with Parkinson's Disease
23 Psychosis." Therein, the Company, in relevant part, stated:

24 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
25 biopharmaceutical company focused on the development and
26 commercialization of innovative medicines to address unmet medical
27 needs in central nervous system (CNS) disorders, today announced that
28 NUPLAZID™ (pimavanserin) is now available for prescription in the
United States. NUPLAZID was approved by the U.S. Food and Drug
Administration (FDA) on April 29, 2016 for the treatment of
hallucinations and delusions associated with Parkinson's disease
psychosis.

NUPLAZID is the first and only drug approved by the FDA for this
indication. NUPLAZID is also the only drug approved by the FDA that
preferentially targets 5-HT_{2A} receptors. These receptors are thought to
play an important role in Parkinson's disease psychosis. The unique
pharmacology of NUPLAZID establishes a new class of drug -
selective serotonin inverse agonists (SSIA) - by not only preferentially
targeting 5-HT_{2A} receptors but also avoiding activity at dopamine and
other receptors commonly targeted by antipsychotics. Typical
Parkinson's disease therapy consists of drugs that stimulate dopamine
to treat patients' motor symptoms such as tremor, muscle rigidity and
difficulty with walking. NUPLAZID does not interfere with patients'
dopaminergic therapy and therefore does not impair their motor
function.

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3 26. On July 29, 2016, ACADIA issued a press release entitled “ACADIA
4 Pharmaceuticals Reports Second Quarter 2016 Financial Results.” Therein, the
5 Company, in relevant part, stated:

6 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
7 biopharmaceutical company focused on the development and
8 commercialization of innovative medicines to address unmet medical
9 needs in central nervous system (CNS) disorders, today announced its
10 unaudited financial results for the second quarter ended June 30, 2016.

11 “The second quarter of 2016 was highlighted by transformative events
12 for ACADIA, including the FDA approval and recent commercial
13 launch of NUPLAZID™,” said Steve Davis, ACADIA’s President and
14 Chief Executive Officer. “We are executing on our plans to bring
15 NUPLAZID to patients in need – our sales specialists have been trained
16 and deployed; our patient and physician support system,
17 NUPLAZIDconnect™, became operational at approval; we are
18 expanding awareness of NUPLAZID among healthcare professionals
19 through a number of initiatives including speaker programs, media and
20 digital campaigns, and symposia at major medical meetings; and we are
21 working with payors to make NUPLAZID available to eligible
22 patients.”

23 **Recent Highlights**

- 24 • NUPLAZID (pimavanserin) approved by the U.S. Food and
25 Drug Administration (FDA) on April 29, 2016 for the treatment
26 of hallucinations and delusions associated with Parkinson’s
27 disease psychosis.
- 28 • NUPLAZID (pimavanserin) made available for prescription
on May 31, 2016 with physicians able to prescribe patients a 30-
day free trial.
- Approximately 135 seasoned sales specialists were onboarded,
trained, and deployed at launch. They have an average of over
eight years of CNS sales experience and 15 years in the
pharmaceutical industry.
- Enrollment completed in a Phase II study exploring the utility of
pimavanserin for the treatment of Alzheimer’s disease psychosis.
Announcement of top-line results from the study expected by the
end of 2016.
- Executing on plans to initiate a Phase II study with pimavanserin
in Alzheimer’s disease agitation in the second half of 2016.

1 **Financial Results**

2 *Revenue*

3 ACADIA reported net product sales of \$97,000 for the three months
4 ended June 30, 2016. No similar net product sales were reported for the
5 comparable period of 2015. NUPLAZID was made available for
6 prescription on May 31, 2016. Through ACADIA’s
7 NUPLAZIDconnect site, physicians are able to prescribe patients a 30-
8 day free trial of NUPLAZID upon initiation of therapy, for which no
9 revenue is recognized.

10 27. On August 4, 2016, ACADIA filed its quarterly report with the SEC on
11 Form 10-Q for the quarter ended June 30, 2016. The Company’s 10-Q was signed
12 by Defendant Davis and reaffirmed the financial results announced in the press
13 release issued on July 29, 2016.

14 28. On November 7, 2016, ACADIA issued a press release entitled
15 “ACADIA Pharmaceuticals Reports Third Quarter 2016 Financial Results.”
16 Therein, the Company, in relevant part, stated:

17 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
18 biopharmaceutical company focused on the development and
19 commercialization of innovative medicines to address unmet medical
20 needs in central nervous system (CNS) disorders, today announced its
21 unaudited financial results for the third quarter ended September 30,
22 2016.

23 “We are very pleased with the launch and are gratified by the positive
24 feedback we have received from physicians, patients, and caregivers on
25 NUPLAZID (pimavanserin),” said Steve Davis, ACADIA’s President
26 and Chief Executive Officer. “We saw solid month-over-month
27 prescription growth, reported increased payor coverage, and continued
28 to expand awareness of NUPLAZID among movement disorder
 specialists, neurologists, and psychiatrists.”

 “In addition, we continue to expand our clinical program with
 pimavanserin. We recently announced the initiation of our SERENE
 study for the treatment of Alzheimer’s disease agitation and our
 ENHANCE-1 study for adjunctive treatment of schizophrenia in
 patients who have an inadequate response to current antipsychotic
 treatment. These studies, together with additional studies we will
 commence later this year, underscore our commitment to improving the
 lives of patients with CNS disorders.”

1 **Recent Highlights**

- 2 • U.S. launch of NUPLAZID commenced May 31, 2016. NUPLAZID is the first and only drug approved by the FDA for
- 3 the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis.
- 4 • NUPLAZID now on Medicare formularies; coverage of NUPLAZID by commercial insurance plans continues to grow.
- 5 • In October 2016, announced the initiation of the SERENE study, a Phase II study with pimavanserin for patients with Alzheimer’s
- 6 disease agitation.
- 7 • In November 2016, announced the initiation of ENHANCE-1, a Phase III study with pimavanserin for adjunctive treatment for
- 8 patients with schizophrenia who are experiencing inadequate response to their current antipsychotic therapy.
- 9 • Completed enrollment of our Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer’s disease
- 10 psychosis. Announcement of top-line results from the study expected by the end of 2016.
- 11 • Presented multiple scientific posters and hosted booth exhibits for healthcare providers and disease education at the World
- 12 Parkinson Congress.
- 13 • Sponsored the National Parkinson’s Foundation Caregiver Summit.
- 14 • Raised approximately \$215.9 million in a common stock offering in August 2016.

15 **Financial Results**

16 *Revenue*

17 ACADIA reported net product sales of \$5.3 million for the three months ended September 30, 2016. No similar net product sales were

18 reported for the comparable period of 2015. NUPLAZID was made available for prescription starting May 31, 2016. Through ACADIA’s

19 NUPLAZIDconnect™ site, upon initiation of therapy, physicians are able to prescribe patients a 30-day free trial of NUPLAZID for which

20 no revenue is recognized.

21 29. On November 7, 2016, ACADIA filed its quarterly report with the SEC

22 on Form 10-Q for the quarter ended September 30, 2016. The Company’s 10-Q was

23 signed by Defendant Young and reaffirmed the financial results announced in the

24 press release issued on November 7, 2016.

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26 30. On February 28, 2017, ACADIA issued a press release entitled

27 “ACADIA Pharmaceuticals Reports Financial Results for the Fourth Quarter and

28

1 Year Ended December 31, 2016.” Therein, the Company, in relevant part, stated:

2 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
3 biopharmaceutical company focused on the development and
4 commercialization of innovative medicines to address unmet medical
5 needs in central nervous system (CNS) disorders, today announced its
6 financial results for the fourth quarter and year ended December 31,
7 2016.

8 “2016 was a transformational year for ACADIA highlighted by the
9 launch of NUPLAZID (pimavanserin) as the first and only drug
10 approved by the FDA for the treatment of hallucinations and delusions
11 associated with Parkinson’s disease psychosis,” said Steve Davis,
12 ACADIA’s President and Chief Executive Officer. “We are pleased
13 with the strong progress of the launch and our execution in bringing
14 this drug to Parkinson’s patients.”

15 “More recently, we announced positive results from our Phase II study
16 with pimavanserin in Alzheimer’s disease psychosis. Pimavanserin has
17 now shown antipsychotic effects in clinical studies in three major CNS
18 disorders: Parkinson’s disease, schizophrenia, and Alzheimer’s disease.
19 These results, combined with the initiation of four new clinical
20 programs, underscore the potential of pimavanserin to improve the
21 lives of patients across multiple CNS disease states and our
22 commitment to explore this potential in broad and substantive clinical
23 programs.”

24 **Recent Highlights**

- 25 • NUPLAZID now available on Medicare formularies for the
26 treatment of Parkinson’s disease psychosis (PD Psychosis);
27 commercial coverage decisions now made for over 60% of
28 commercial lives and continue to grow.
- Positive top-line results from our Phase II study exploring the
utility of pimavanserin for the treatment of Alzheimer’s disease
psychosis announced in December 2016.
- Initiated the SERENE study, a 430-patient study evaluating
pimavanserin for the treatment of Alzheimer’s disease agitation.
- Initiated the ENHANCE-1 study, a 380-patient study evaluating
pimavanserin for adjunctive treatment of schizophrenia in
patients with an inadequate response to their current
antipsychotic therapy.
- Initiated the ADVANCE study, a 380-patient study evaluating
pimavanserin for adjunctive treatment in patients with negative
symptoms of schizophrenia.
- Initiated the CLARITY study, a 188-patient study evaluating
pimavanserin for adjunctive treatment in patients with major
depressive disorder who have an inadequate response to standard
antidepressant therapy.

29 **Financial Results**

30 *Revenue*

31 ACADIA reported net product sales of \$12.0 million for the fourth

1 quarter of 2016. NUPLAZID was launched commercially in May 2016,
2 so there were no similar product sales for the comparable quarter of
3 2015. Through ACADIA's NUPLAZIDconnect™ site, upon initiation
4 of therapy, physicians have been able to prescribe patients a 30-day
5 free trial of NUPLAZID for which no revenue is recognized.

6 31. On February 28, 2017, ACADIA filed its annual report with the SEC
7 on Form 10-K for the year ended December 31, 2016. The Company's 10-K was
8 signed by Defendant Davis and reaffirmed the financial results announced in the
9 press release issued on February 28, 2017.

10 32. On May 9, 2017, ACADIA issued a press release entitled "ACADIA
11 Pharmaceuticals Reports First Quarter 2017 Financial Results." Therein, the
12 Company, in relevant part, stated:

13 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
14 biopharmaceutical company focused on the development and
15 commercialization of innovative medicines to address unmet medical
16 needs in central nervous system (CNS) disorders, today announced its
17 unaudited financial results for the first quarter ended March 31, 2017.

18 "We're very pleased with our strong start to 2017," said Steve Davis,
19 ACADIA's President and Chief Executive Officer. "The use of
20 NUPLAZID® in Parkinson's disease psychosis continues to expand as
21 brand awareness among neurologists, psychiatrists, and other
22 healthcare providers grows. We also continue to advance our ongoing
23 clinical studies in Alzheimer's disease agitation, schizophrenia
24 inadequate response, schizophrenia negative symptoms, and major
25 depressive disorder, and we look forward to moving our Alzheimer's
26 disease psychosis program into Phase III in the second half of 2017."

27 **Recent Highlights**

- 28 • Net revenue for the first quarter of 2017 of \$15.3 million, an increase of 28% from the fourth quarter of 2016.
- NUPLAZID (pimavanserin) available on Medicare formularies for the treatment of Parkinson's disease psychosis (PD Psychosis); commercial coverage decisions grew to over 90% of commercial lives.
- Expanded penetration into the long-term care market with 25 additional long-term care sales specialists; ACADIA currently has approximately 155 total sales specialists.
- Continued to execute on broad clinical development program with ongoing studies in Alzheimer's disease agitation, schizophrenia inadequate response, schizophrenia negative symptoms, and major depressive disorder.

- 1 • Plan to advance Alzheimer’s disease psychosis (AD Psychosis) program into Phase III in second half of 2017.
- 2 • Presented data on NUPLAZID in PD Psychosis at the American Association for Geriatric Psychiatry Annual Meeting.
- 3 • Appointed Michael J. Yang as Executive Vice President, Chief Commercial Officer.

4 **Financial Results**

5 *Revenue*

6 ACADIA reported NUPLAZID net product sales of \$15.3 million for
7 the three months ended March 31, 2017. NUPLAZID was first made
8 available for prescription starting in May 2016 and there were no
9 similar net product sales for the comparable period of 2016. ACADIA
10 reports product sales when its specialty pharmacy partners dispense
11 NUPLAZID to a patient based on the fulfillment of a prescription or its
12 specialty distributor partners sell NUPLAZID to a government facility,
13 long-term care pharmacy or in-patient hospital pharmacy. As of March
14 31, 2017, the company had \$4.1 million of deferred product revenue,
15 net of distribution fees, for product it had shipped to its distribution
16 partners that had not yet sold-through the distribution channel.
17 At December 31, 2016, the company had \$2.6 million of deferred
18 product revenue, net of distribution fees.

19 33. On May 9, 2017, ACADIA filed its quarterly report with the SEC on
20 Form 10-Q for the quarter ended March 31, 2017. The Company’s 10-Q was signed
21 by Defendant Young and reaffirmed the financial results announced in the press
22 release issued on May 9, 2017.

23 34. On August 8, 2017, ACADIA issued a press release entitled “ACADIA
24 Pharmaceuticals Reports Second Quarter 2017 Financial Results.” Therein, the
25 Company, in relevant part, stated:

26 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
27 biopharmaceutical company focused on the development and
28 commercialization of innovative medicines to address unmet medical
needs in central nervous system (CNS) disorders, today announced its
unaudited financial results for the second quarter ended June 30, 2017.

“Our commercial efforts continue to drive strong financial performance with solid market uptake for NUPLAZID in patients with Parkinson’s disease psychosis,” said Steve Davis, ACADIA’s President and Chief Executive Officer. “Following positive data from our Phase II study in Alzheimer’s disease psychosis and recently completed End-of-Phase II meeting with the FDA, we are excited to start our Phase III program in

1 the next couple of months.”

2 During the second quarter of 2017, ACADIA generated \$30.5
3 million of net product sales of NUPLAZID, which includes the one-
4 time recognition of \$3.6 million associated with the transition to the
sell-in revenue recognition method of accounting from the sell-through
method.

5 * * *

6 **Financial Results**

7 *Revenue*

8 Net product sales of NUPLAZID, which was first made available for
9 prescription starting in May 2016, were \$30.5 million for the three
10 months ended June 30, 2017 compared to \$0.1 million for the three
11 months ended June 30, 2016. For the six months ended June 30,
2017 and 2016, ACADIA reported NUPLAZID net product sales
of \$45.8 million and \$0.1 million, respectively.

12 35. On August 8, 2017, ACADIA filed its quarterly report with the SEC on
13 Form 10-Q for the quarter ended June 30, 2017. The Company’s 10-Q was signed
14 by Defendant Young and reaffirmed the financial results announced in the press
15 release issued on August 8, 2017.
16

17 36. On November 7, 2017, ACADIA issued a press release entitled
18 “ACADIA Pharmaceuticals Reports Third Quarter 2017 Financial Results.”
19
20 Therein, the Company, in relevant part, stated:

21 ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a
22 biopharmaceutical company focused on the development and
23 commercialization of innovative medicines to address unmet medical
needs in central nervous system (CNS) disorders, today announced its
unaudited financial results for the third quarter ended September 30,
2017.

24 “Our results this quarter reflect strong growth for NUPLAZID for
25 Parkinson’s disease psychosis,” said Steve Davis, ACADIA’s President
26 and Chief Executive Officer. “We also recently advanced our clinical
27 portfolio with the initiation of our Phase III study of pimavanserin for
dementia-related psychosis and were pleased to receive FDA
Breakthrough Therapy Designation for this program. If this study is
28 successful, we believe pimavanserin will provide an important benefit
to patients with dementia-related psychosis who currently have
no FDA-approved treatments available to them.”

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Recent Highlights

- Initiated pivotal Phase III HARMONY Study with pimavanserin in dementia-related psychosis in October 2017.
- FDA granted Breakthrough Therapy Designation to pimavanserin for the treatment of dementia-related psychosis in October 2017. This is the second Breakthrough Therapy Designation for pimavanserin.
- Presented Phase II data with pimavanserin in Alzheimer’s disease psychosis at the Symposium, “The Importance of Serotonin in Alzheimer’s Disease Psychosis and the Role of Pimavanserin,” at the Clinical Trials on Alzheimer’s Disease (CTAD) meeting in Boston in November 2017.
- In addition to dementia-related psychosis, ACADIA continues to advance its broad clinical development program with ongoing studies in schizophrenia inadequate response, schizophrenia negative symptoms, and major depressive disorder.

Financial Results

Revenue

Net product sales of NUPLAZID, which was first made available for prescription starting in May 2016, were \$35.6 million for the three months ended September 30, 2017 compared to \$5.3 million for the three months ended September 30, 2016. For the nine months ended September 30, 2017 and 2016, ACADIA reported NUPLAZID net product sales of \$81.3 million and \$5.4 million, respectively.

37. On November 7, 2017, ACADIA filed its quarterly report with the SEC on Form 10-Q for the quarter ended September 30, 2017. The Company’s 10-Q was signed by Defendant Young and reaffirmed the financial results announced in the press release issued on November 7, 2017.

38. The above statements identified in ¶¶24-37 were materially false and/or misleading, and failed to disclose material adverse facts about the Company’s business, operations, and prospects. Specifically, Defendants failed to disclose: (1) that adverse events and safety concerns related to NUPLAZID threatened the drug’s initial and continuing FDA approval; (2) that ACADIA engaged in business practices likely to attract regulatory scrutiny; and (3) that, as a result of the

1 foregoing, Defendants' statements about ACADIA's business, operations, and
2 prospects, were materially false and/or misleading and/or lacked a reasonable basis.

3
4 39. On February 27, 2018, ACADIA announced fourth quarter 2017
5 NUPLAZID sales of \$43.6 million, which was approximately \$720,000 below
6 consensus estimates. ACADIA issued a press release entitled "ACADIA
7
8 Pharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results."
9 Therein, the Company, in relevant part, stated:

10 ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical
11 company focused on the development and commercialization of
12 innovative medicines to address unmet medical needs in central
13 nervous system (CNS) disorders, today announced its financial results
14 for the fourth quarter and year ended December 31, 2017.

15 "Our 2017 results reflect the robust uptake of NUPLAZID
16 (pimavanserin) in the treatment of Parkinson's disease psychosis,"
17 said Steve Davis, ACADIA's President and Chief Executive Officer.
18 "We were also very pleased to receive Breakthrough Therapy
19 Designation from the FDA as we explore the utility of pimavanserin in
20 dementia-related psychosis, where no drug is currently approved. This
21 is the second Breakthrough Therapy Designation for pimavanserin."

22 "As we look to 2018, we anticipate continued strong volume growth for
23 NUPLAZID. In addition, we look forward to advancing our late-stage
24 clinical programs in dementia-related psychosis, schizophrenia
25 inadequate response and schizophrenia negative symptoms, as well as
26 sharing the top-line results of our CLARITY study in major depressive
27 disorder in the second half of 2018."

28 **Recent Highlights**

- Initiated a national direct-to-consumer disease awareness TV ad campaign to educate patients and caregivers about Parkinson's disease psychosis (PD Psychosis) in November 2017.
- Initiated pivotal Phase 3 HARMONY Study with pimavanserin in dementia-related psychosis in October 2017.
- Received a second Breakthrough Therapy Designation from the FDA for pimavanserin in October 2017. This designation is for the treatment of dementia-related psychosis.
- Presented Phase 2 data with pimavanserin in Alzheimer's disease psychosis at the Clinical Trials on Alzheimer's Disease (CTAD) meeting in Boston in November 2017.
- Appointed Damien McDevitt, Ph.D., Senior Vice President, Corporate Development.

1 **Financial Results**

2 *Revenue*

3 Net product sales of NUPLAZID, which was first made available for
4 prescription starting in May 2016, were \$43.6 million for the fourth
5 quarter of 2017, an increase of 263% as compared to \$12.0
6 million reported for the fourth quarter of 2016. For the year
7 ended December 31, 2017, ACADIA reported NUPLAZID net product
8 sales of \$124.9 million, an increase of \$107.6 million, or 622% from
9 the \$17.3 million reported for the year ended December 31, 2016.

10 40. On February 27, 2018, ACADIA filed its annual report with the SEC
11 on Form 10-K for the year ended December 31, 2017. The Company’s 10-K was
12 signed by Defendant Davis and reaffirmed the financial results announced in the
13 press release issued on February 27, 2018.

14 41. On this news, ACADIA’s share price fell \$6.24 per share, or 20%, to
15 close at \$24.92 per share on February 28, 2018, on unusually heavy trading volume.

16 42. The above statements identified in ¶¶39-40 were materially false and/or
17 misleading, and failed to disclose material adverse facts about the Company’s
18 business, operations, and prospects. Specifically, Defendants failed to disclose: (1)
19 that adverse events and safety concerns related to NUPLAZID threatened the drug’s
20 initial and continuing FDA approval; (2) that ACADIA engaged in business
21 practices likely to attract regulatory scrutiny; and (3) that, as a result of the
22 foregoing, Defendants’ statements about ACADIA’s business, operations, and
23 prospects, were materially false and/or misleading and/or lacked a reasonable basis.

24 43. On April 9, 2018, CNN reported that “[p]hysicians, medical researchers
25 and other experts told CNN that they worried that [NUPLAZID] had been approved
26 and other experts told CNN that they worried that [NUPLAZID] had been approved
27 and other experts told CNN that they worried that [NUPLAZID] had been approved
28 and other experts told CNN that they worried that [NUPLAZID] had been approved

1 too quickly, based on too little evidence that it was safe or effective. And given
2 these mounting reports of deaths, they say that more needs to be done to assess
3
4 Nuplazid's true risks." In greater part, the article stated:

5 Nuplazid's review was being expedited because it had been designated
6 a "breakthrough therapy" -- meaning that it demonstrated "substantial
7 improvement" in patients with serious or life-threatening diseases
8 compared to treatments already on the market. Congress created this
9 designation in 2012 in an effort to speed up the FDA's approval
10 process, which has long been criticized for being too slow. Around 200
11 drugs have been granted this designation since its creation.

12 Still, to recommend approval, the advisory committee would have to
13 find that the drug's potential benefits outweighed its risks for its
14 intended patients.

15 Some FDA officials concluded that Nuplazid's public health benefit
16 was enough to merit approval of the drug. Their argument echoed the
17 pleas of family members and caregivers like Tyne: It could possibly
18 help patients with no other alternative. Several of the people who spoke
19 said their loved ones had been transformed during the clinical trials,
20 though some said there was no way for them to know whether they
21 were on Nuplazid or a placebo.

22 But the physician who led the FDA's medical review, Dr. Paul
23 Andreason, warned that patients taking the drug during the company's
24 clinical trials experienced serious outcomes, including death, at more
25 than double the rate of those taking the placebo. The company's limited
26 testing, he said, had not convinced him that the benefits outweighed the
27 risks.

28 While Tyne had heard about these risks, he said he "discounted death
as a real statistical possibility" and was willing to try anything to help
his mother.

"I have two young children who love their grandmother," he told the
committee. "If nothing is done to bring her back to some semblance of
normalcy, my children will never remember their grandmother for who
she is: a loving, funny, caring woman who has improved the lives of all
of the loved ones who surround her. Please, I beg you, do not deprive
my children and their grandmother of experiencing that love."

'You have to take it seriously'

The committee voted 12-2 and recommended that the FDA approve
Nuplazid for the treatment of Parkinson's disease psychosis based on a
six-week study of about 200 patients. Three previous studies of the
drug did not show that it was effective, Andreason said in his medical
review, though they showed similar risk.

1 Even some committee members who voted in favor of the drug
2 expressed reservations, according to the hearing transcript. “I guess I’m
3 hoping that the risks are going to be small, and I think the benefits for
4 some of these people who are very sick and whose families are affected
5 by this, I think they’re probably willing to take that risk,” one physician
6 stated. Another committee member said she wouldn’t have voted for
7 the drug’s approval if there had been a safe and effective alternative on
8 the market. A third made a “plea” to the FDA to “consider a large
9 observational study so we can ensure that, once it goes into real-world
10 use, that the benefits will outweigh the risks.”

11 It hit the market in June 2016. As caregivers and family members
12 rushed to get their loved ones on it, sales climbed to roughly \$125
13 million in 2017.

14 Tyne got his mother on the drug as soon as it became available. But
15 after trying it for months, he says he was devastated to see that it was
16 doing nothing to halt the awful progression of the disease, and her
17 hallucinations became more frequent and harder to manage. “She has
18 gone straight downhill to the point she really can’t function at all,” he
19 said.

20 Shortly after the drug’s release, patients’ family members, doctors and
21 other health care professionals started reporting “adverse events”
22 possibly linked to the medication -- including deaths, life-threatening
23 incidents, falls, insomnia, nausea and fatigue. In more than 1,000
24 reports, patients continued to experience hallucinations while on
25 Nuplazid.

26 In November, an analysis released by a nonprofit health care
27 organization, the Institute for Safe Medication Practices, warned that
28 244 deaths had been reported to the FDA between the drug’s launch
and March 2017. The organization also noted that hundreds of reports
suggested the drug was “not providing the expected benefit” or
potentially worsening the condition.

Tracked by the FDA, these so-called “adverse event reports” document
deaths, side effects and other issues, and can be made directly by
consumers, caregivers and other medical professionals. Reports are
submitted to either the FDA or to the drugmaker, which is required to
pass along any it receives to the federal government. In some cases, the
person filing the report is convinced the side effects were caused by the
drug; in others, the reporter ascribes no cause but notes that the patient
was on the drug.

An adverse event report does not mean that a suspected medication has
been ruled the cause of harm and is typically not the result of an official
investigation. But the FDA uses the information to monitor potential
issues with a drug and can take action as needed -- updating a
medication’s label, for instance, or restricting its use or pulling it off
the market.

After analyzing the adverse event data for Nuplazid, the Institute for
Safe Medication Practices concluded that this batch of reports
“reinforces the concerns of those who warned that (Nuplazid) might do

1 more harm than good.” Thomas Moore, senior scientist for drug safety
2 and policy for the nonprofit, said the deaths are an “important warning
3 signal” and warrant further review by the FDA -- and possible action,
4 depending on what the review finds.

5 Since the institute released its analysis, FDA data shows that the
6 number of reported deaths has risen to more than 700. As of last June,
7 Nuplazid was the only medication listed as “suspect” in at least 500 of
8 the death reports.

9 Physicians, medical researchers and other experts told CNN that they
10 worried that the drug had been approved too quickly, based on too little
11 evidence that it was safe or effective. And given these mounting reports
12 of deaths, they say that more needs to be done to assess Nuplazid’s true
13 risks.

14 “This is almost unheard of, to have this many deaths reported,” said
15 Diana Zuckerman, founder and president of the nonprofit thinktank the
16 National Center for Health Research, adding that because reports are
17 voluntary, potential problems may be underreported. “You just don’t
18 see this with most new drugs -- you don’t see all these reports -- so you
19 have to take it seriously.”

20 44. On this news, ACADIA’s share price fell \$5.03 per share, or 23.4%, to
21 close at \$16.50 per share on April 9, 2018, on unusually heavy trading volume.

22 45. On April 10, 2018, ACADIA issued a press release entitled “ACADIA
23 Statement Regarding the Efficacy and Safety of NUPLAZID.” Therein, the
24 Company stated:

25 The safety of patients has always been, and continues to be ACADIA’s
26 top priority. NUPLAZID® was approved by the FDA for the treatment
27 of hallucinations and delusions associated with Parkinson’s disease
28 psychosis (PDP) based on a pivotal Phase 3 study and other supportive
studies that demonstrate its efficacy and safety. The clinical
development program for NUPLAZID involved 25 clinical studies in
greater than 1,200 patients, comprising over 600 PDP patients (with
approximately 170 patients treated for at least two years), thus
presenting the largest clinical safety database in PDP patients to date.
We continually analyze new data to ensure the safety of NUPLAZID
and the ongoing evaluation has revealed no change in the benefit/risk
profile described in the NUPLAZID Prescribing Information.

Approximately one million people in the United States live with
Parkinson’s disease. More than 50 percent of them will experience PDP
symptoms over the course of the disease. As the only drug currently
approved by the FDA for the treatment of hallucinations and delusions
associated with PDP, NUPLAZID is filling an important and
previously unmet need and offers hope to those with PDP and the

1 people who care for them. We remain confident in the efficacy and
2 safety of NUPLAZID that supported its approval by the FDA and stand
firmly behind it.

3 46. The above statements identified in ¶45 were materially false and/or
4 misleading, and failed to disclose material adverse facts about the Company's
5 business, operations, and prospects. Specifically, Defendants failed to disclose: (1)
6 that adverse events and safety concerns related to NUPLAZID threatened the drug's
7 initial and continuing FDA approval; (2) that ACADIA engaged in business
8 practices likely to attract regulatory scrutiny; and (3) that, as a result of the
9 foregoing, Defendants' statements about ACADIA's business, operations, and
10 prospects, were materially false and/or misleading and/or lacked a reasonable basis.
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14 47. On April 25, 2018, CNN reported that the FDA was re-examining the
15 safety of NUPLAZID. In greater part, the article stated:

16 The Food and Drug Administration says it is re-examining the safety of
17 a medication that was approved despite concerns that not enough was
known about the drug's risks.

18 In response to questioning at a budget hearing last week, FDA
19 Commissioner Scott Gottlieb told members of Congress that he would
20 "take another look" at Nuplazid, which is the only drug approved to
21 treat hallucinations and delusions associated with Parkinson's disease
22 psychosis. The medication has been cited as a so-called "suspect"
medication in hundreds of deaths voluntarily reported by caregivers,
doctors and other medical professionals since it hit the market, as
highlighted in a recent CNN report.

23 The FDA told CNN this week that the agency had already begun
24 conducting a new evaluation of the medication when Gottlieb was
questioned about it at the hearing. The agency said the review had
started several weeks ago.

25 "What does it take for a drug like this to be taken off the market?"
26 asked US Rep. Rosa DeLauro, a member and former chair of the
27 congressional subcommittee responsible for funding and overseeing the
FDA.

28 DeLauro pressed Gottlieb for answers on his agency's response to the
safety concerns surrounding Nuplazid.

1 “How many more adverse events do we have to have reported? How
2 many people, quite frankly, have to die? Why does the industry always
3 take precedence over public health and safety?”

4 Tracked by the FDA, the adverse event reports cited by DeLauro do not
5 mean that a suspected medication has been ruled the cause of harm and
6 are typically not the result of official investigations. But the FDA uses
7 the information to monitor potential issues with a drug and can take
8 action as needed: updating a medication’s label, for instance, or
9 restricting its use. In rare cases, the agency can even pull a drug off the
10 market.

11 When asked by CNN about what prompted the FDA’s new evaluation
12 of Nuplazid, the agency said the decision was based on a number of
13 factors but wouldn’t say what those factors were. Instead, it would only
14 comment generally, saying that it identifies “potential signals of serious
15 risk/new safety information” in part by using adverse event data and
16 that the agency is not suggesting physicians stop prescribing the drug
17 or take patients off of it while a safety evaluation is taking place.

18 The FDA has noted that the death reports citing Nuplazid have
19 typically involved elderly patients with advanced-stage Parkinson’s
20 disease who suffered from numerous medical conditions and often take
21 other medications that can increase the risk of death.

22 But physicians, researchers and other medical experts told CNN that
23 the high number of reports deserved a closer look to determine whether
24 they were related to the drug. They also recommended further testing of
25 Nuplazid, worrying that the drug had been approved too quickly, based
26 on too little evidence that it was safe or effective.

27 48. On this news, ACADIA’s share price fell \$4.27 per share, or 21.9%, to
28 close at \$15.20 per share on April 25, 2018, on unusually heavy trading volume.

49. On April 27, 2018, ACADIA published a statement entitled “ACADIA
Pharmaceuticals Issues Statement Reaffirming Benefit/Risk Profile of NUPLAZID.”

Therein, the Company, in relevant part, stated:

NUPLAZID® (pimavanserin) is the only medicine approved in the
United States to treat hallucinations and delusions associated with
Parkinson’s disease psychosis. NUPLAZID was approved by the FDA
based on a pivotal Phase 3 study that demonstrated clinically robust and
highly statistically significant efficacy, combined with other supportive
studies. We are confident in NUPLAZID’s efficacy and positive
benefit/risk profile and stand firmly behind it.

ACADIA’s top priority has been, and continues to be, patient safety.
NUPLAZID was approved and launched in 2016. As the manufacturer

1 of a newly launched drug, we are routinely in contact with the FDA
2 regarding requests for additional information on NUPLAZID, including
3 postmarketing safety surveillance information as part of the FDA's
4 ongoing safety monitoring.

5 In a statement released to the media on April 10, 2018, the FDA stated,
6 "The FDA continues to monitor adverse events reported with
7 NUPLAZID that are submitted to the FDA Adverse Event Reporting
8 System (FAERS). We have noted that the cases typically involve
9 geriatric patients with advanced-stage Parkinson's disease, as well as
10 numerous medical conditions, who are frequently taking concomitant
11 medications with risks for serious adverse events, including death.
12 Based on these data, the FDA has, at this time, not identified a specific
13 safety issue that is not already adequately described in the product
14 labeling."

15 On April 25, 2018, the FDA stated that its evaluation does not mean the
16 Agency has determined the medicine has a new risk and does not
17 suggest healthcare providers should not prescribe it nor that patients
18 should stop taking the medication. The Agency also has confirmed this
19 statement does not represent a change from the safety review and
20 monitoring activities the FDA referred to in its statement of April 10.
21 As always, we will continue to work with the FDA and medical
22 community to answer any questions related to NUPLAZID.

23 ACADIA collects and analyzes postmarketing events for NUPLAZID
24 as part of our ongoing commitment to monitor the medication's safety
25 profile. These events are submitted to the FDA and incorporated into
26 the FDA's FAERS public reporting system. Because NUPLAZID is
27 distributed through a specialty distribution channel, we have frequent
28 (in most cases monthly) contact with patients and caregivers through
our distribution partners. This increased interaction naturally results in
dramatically higher adverse event collection and reporting compared to
products without such a distribution method. Approximately 93 percent
of the reported adverse events associated with NUPLAZID are
considered "solicited" due to this direct interaction with patients and
caregivers, while only approximately 7 percent of these events are
considered "spontaneous" reports, which are voluntary reports
originating from consumers or healthcare professionals. In contrast,
most other antipsychotics are distributed through retail channels, which
rely almost entirely on "spontaneous" reporting. Consequently, only a
small fraction of actual adverse events are collected for these drugs.

50. On May 4, 2018, ACADIA issued a press release entitled "CADIA
Pharmaceuticals Reports First Quarter 2018 Financial Results." Therein, the
Company, in relevant part, stated:

ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical
company focused on the development and commercialization of
innovative medicines to address unmet medical needs in central
nervous system (CNS) disorders, today announced its financial results

1 for the first quarter ended March 31, 2018.

2 “NUPLAZID delivered strong performance in the first quarter of 2018.
3 Sequential volume growth of 13.5% drove sequential revenue growth
4 of 12% as health care providers and patients continue to experience the
5 benefits of NUPLAZID in treating the symptoms of Parkinson’s
6 disease psychosis,” said Steve Davis, ACADIA’s President and Chief
7 Executive Officer. “Our R&D organization also continued to advance
8 our late-stage clinical programs in four major CNS indications and we
9 look forward to providing top-line results from our Phase 2 study of
10 pimavanserin in major depressive disorder in the second half of 2018.
11 We remain confident in the tremendous opportunities ahead for
12 NUPLAZID, which is early in its growth phase.”

8 **Recent Highlights**

- 9 • Announced poster presentations at the 2018 American Academy
10 of Neurology (AAN) Annual Meeting of clinical experience data
11 from two independent studies of NUPLAZID (pimavanserin),
12 including a retrospective chart review conducted by researchers
13 at Vanderbilt University Medical Center and a survey of real-life
14 experiences conducted by researchers from the
15 Parkinson’s Disease and Movement Disorder Center at Henry
16 Ford Hospital.
- 17 • Reported results of a survey conducted with the Parkinson and
18 Movement Disorder Alliance revealing the serious impact of
19 non-movement symptoms like hallucinations and delusions on
20 quality of life of patients with Parkinson’s disease and their
21 caregivers.
- 22 • Advanced broad clinical development programs with ongoing
23 studies in dementia-related psychosis, schizophrenia inadequate
24 response, schizophrenia negative symptoms and major
25 depressive disorder with plans to announce top-line results of a
26 Phase 2 study of pimavanserin in major depressive disorder in
27 the second half of 2018.
- 28 • Appointed Elena Ridloff, CFA, as Senior Vice President,
Investor Relations.

20 **Financial Results**

21 *Revenue*

22 Net sales of NUPLAZID were \$48.9 million for the first quarter of
23 2018, an increase of 220% as compared to \$15.3 million reported for
24 the first quarter of 2017.

25 51. On May 4, 2018, ACADIA filed its quarterly report with the SEC on
26 Form 10-Q for the quarter ended June 30, 2016. The Company’s 10-Q was signed
27 by Defendant Young and reaffirmed the financial results announced in the press
28 release issued on May 4, 2018.

1 52. The above statements identified in ¶¶49-51 were materially false and/or
2 misleading, and failed to disclose material adverse facts about the Company’s
3 business, operations, and prospects. Specifically, Defendants failed to disclose: (1)
4 that adverse events and safety concerns related to NUPLAZID threatened the drug’s
5 initial and continuing FDA approval; (2) that ACADIA engaged in business
6 practices likely to attract regulatory scrutiny; and (3) that, as a result of the
7 foregoing, Defendants’ statements about ACADIA’s business, operations, and
8 prospects, were materially false and/or misleading and/or lacked a reasonable basis.
9
10

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12 **Disclosures at the End of the Class Period**

13 53. On July 9, 2018, the SIRF published a report entitled “Acadia
14 Pharmaceuticals: This Is Not a Pharmaceuticals Company.” Therein, the SIRF
15 stated that “evidence is mounting that something is horribly wrong with Acadia’s
16 sole drug, Nuplazid, an antipsychotic for Parkinson’s disease patients who
17 experience episodic hallucinations and delusions” and that “Acadia has
18 accomplished its growth in ways that have attracted intense regulatory scrutiny for
19 other drug companies” including “dispensing wads of cash to doctors to incentivize
20 prescription writing and downplaying mounting reports of patient deaths.” In
21 greater part, SIRF stated:
22
23
24

25 Central to Acadia’s marketing is promotion of the faulty illusion that
26 Nuplazid received FDA approval like any other drug — after
27 successfully passing a series of clinical trials and evaluations for the
28 efficacy and safety of its target population. But that’s not the case:
Nuplazid essentially tiptoed into the market through the FDA’s
equivalent of the cellar door, a legal but unusual method of entry. In
other words, the mounting fatalities reported by CNN — and the

1 spiraling costs for the drug that Medicare and private insurance payers
2 are reimbursing — would never have occurred if Nuplazid’s
3 manufacturer had followed the FDA’s standard drug-approval
4 practices.

5 * * *

6 Nuplazid, when tested on people, has been a bust from the very start.
7 The drugmaker has had a brutal time demonstrating that the medication
8 works better than a sugar pill. For example, Nuplazid’s first clinical
9 trial closed in March 2007, without any posting of results. The drug’s
10 third trial ended in March 2014 but did not indicate any
11 meaningful statistical difference between the medication and a placebo.

12 Statistically speaking, a drug trial whose range of results include zero is
13 judged to be a failure in that the drug’s therapeutic benefits are deemed
14 to be too small to be of medical consequence.

15 Faced with a third failure, Acadia’s management might have decided it
16 had reached the end of the road in trying to successfully develop the
17 drug. But due to a provision of the Food and Drug Administration
18 Safety and Innovation Act, however, in August 2014 Acadia was able
19 to get Nuplazid classified as a breakthrough therapy, a status conferred
20 on therapies with “substantial treatment effects” in their initial clinical
21 tests.

22 It was a curious decision, given Nuplazid’s track record and the FDA’s
23 plainly stated requirement for a breakthrough therapy to have
24 “substantial treatment effects observed in early clinical development.”

25 For the FDA’s part, Dr. Mitchell Mathis, the agency’s division director
26 of psychiatry products, told the panel reviewing Nuplazid in March
27 2016 that awarding the breakthrough designation hinged on the fact
28 that no other FDA-approved drugs existed for treating Parkinson’s
disease psychosis, as well as the frequency that these patients were
being placed in nursing homes, which he called “a harbinger of death.”

More baffling still was the FDA’s willingness to assess whether
Nuplazid worked based on “a negotiated evidentiary standard” that
eliminated long-standing evaluation criteria.

In a November analysis, Quarter Watch, a publication of the Institute
for Safe Medication Practices, flagged several ways the approval
process of Nuplazid was unusual. For example, the FDA permitted the
drug’s efficacy to be measured against an index of nine psychotic
symptoms — as opposed to the standard 20-point scale — and the
patients in the study were exclusively advanced cases (the most likely
to be responsive to any drug). The agency also allowed Acadia to stage
only a single trial (rather than the usual two) and to run it just in North
America, where its previous results had been marginally stronger.

The physician responsible for leading the FDA’s medical review of
Nuplazid, Dr. Paul Andreason, recommended against the medication’s
approval, asserting there was an “unacceptably increased, drug-related,
safety risk of mortality and serious morbidity.” Andreason worked for

1 26 years for the U.S. Public Health Service until leaving it in 2016; he
2 spent 13 years with the FDA. His no vote was unusual in that it
3 publicly revealed fault lines inside the division over what constitutes an
4 appropriate level of patient risk.

5 Presumably, Nuplazid would not have been given a breakthrough
6 therapy designation if the FDA's psychiatry product unit's leadership
7 thought the drug was unlikely to win approval. As ProPublica recently
8 described, over the last several years the FDA's approach to the review
9 process for Nuplazid and a series of other drugs has shifted to active
10 cooperation with pharmaceutical companies in getting their drugs
11 commercially launched — and away from serving as a strict arbiter of
12 science and as a guardian of consumer safety.

13 * * *

14 Over the six months that Nuplazid was commercially available in 2016,
15 Acadia spent \$609,556 on consulting, speaking and travel and lodging
16 payments to 1,578 doctors: Pomona, New York, psychiatrist Dr. Leslie
17 Citrome's \$25,690 payout amounted to the largest sum, followed by the
18 \$19,142 paid to Dr. Khashayar Dashtipour, a Loma Linda, California-
19 based neurologist.

20 But what a difference a year makes.

21 For 2017, Acadia paid more than \$8.6 million to 7,051 physicians, with
22 62 doctors receiving more than \$50,000 apiece, and 26 receiving at
23 least \$100,000 each.

24 The leading recipient of Acadia cash last year was Dr. Neal
25 Hermanowicz, an Irvine, California-based movement
26 disorders specialist who took in \$180,123, a handsome improvement
27 over 2016's \$10,421. The runner up was psychiatrist Dr. Jason
28 Kellogg, of Santa Ana, California, who was paid \$166,259. (In
contrast, the \$25,690 that Dr. Citrome received in 2016, which was the
biggest payout for that year, would have ranked as only the 104th
largest payment to doctors if it had been given out in 2017.)

Given the fact that Acadia hired a significant number of former Avanir
sales staffers, a substantial number of doctors have ended up receiving
consulting payments from both Avanir and Acadia in the same calendar
year: A total of 31 did in 2017, as did 29 in 2016. Out of that group, a
dozen doctors took in \$5,000 apiece or more from the two companies in
2017. Just six did in 2016.

Acadia's payments in 2017, according to the Centers for Medicare and
Medicaid Services' Open Payments database, were almost entirely for
consulting, save \$522,935 for food and beverage expenses. (Other
payment categories the centers track include "honorariums," such as
fees for lecturing to other medical professionals, or "education," when
the company covers the expense of distributing a journal article or
staging a presentation at a conference.) Despite Acadia's discussions
about supporting research on Nuplazid, the company's appetite for
external or independent research sharply declined last year. It spent
just \$197,587 on doctors' research projects, in contrast with

1 its \$817,613 outlay in 2016. (Avanir went in the other
2 direction, devoting \$7.61 million to research last year and \$4.36 million
to payments to doctors.)

3 Since Acadia doesn't release Nuplazid's prescription count, Medicare
4 Part D data is the only way to observe prescriber behavior. To that end,
5 overlaying Medicare Part D prescription volume from 2016 (the latest
6 period for which data is available) against the Centers for Medicare and
7 Medicaid Services Open Payments data for 2016 and 2017 illuminates
8 a few things.

9 There's a good deal of overlap between those who received Acadia
10 consulting fee payments in 2016 and 2017 and the individuals who
11 prescribed Nuplazid with some frequency in 2016. For instance, in
12 2016, 14 of the 25 most frequent prescribers of Nuplazid to patients
covered by Medicaid Part D received "consulting fees" in 2017 worth
13 more than \$1.21 million in total.

14 Almost 37 percent of Acadia's \$1.21 million in consulting fee
15 payments, or \$443,014, went to three neurologists who conducted
16 Acadia-funded studies on Nuplazid and published journal articles about
17 their findings: Dr. Neal Hermanowicz; Dr. Stuart Hal Isaacson of Boca
18 Raton, Florida; and Dr. Rajesh Pahwa of Kansas City, Kansas.

19 Pittsburgh-based Dr. Susan Baser, a leading prescriber of Nuplazid to
20 patients paying for it via Medicaid Part D, told the Southern
21 Investigative Reporting Foundation, "It's the only drug addressing
22 [Parkinson's disease psychosis] and we've had positive effects in some
23 patients." She added, "Personally I think it's a good drug despite the
24 noise about adverse events that's out there."

25 Baser, who did not receive any consulting fees from Acadia in 2016
26 and 2017, expressed surprise at the size of the payments that some of
27 her peers received from the company. "I work 60 hours per week. I
28 don't know how they have the time. I'm just too busy for any of that."

54. On this news, ACADIA's share price fell \$1.21 per share, or 6.8%, to
close at \$16.63 per share on July 9, 2018, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

55. 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 persons and
entities that acquired ACADIA securities between April 29, 2016 and July 9, 2018,
inclusive, and who were damaged thereby (the "Class"). Excluded from the Class

1 are Defendants, the officers and directors of the Company, at all relevant times,
2 members of their immediate families and their legal representatives, heirs,
3 successors, or assigns, and any entity in which Defendants have or had a controlling
4 interest.
5

6 56. The members of the Class are so numerous that joinder of all members
7 is impracticable. Throughout the Class Period, ACADIA's common stock actively
8 traded on the NASDAQ. While the exact number of Class members is unknown to
9 Plaintiff at this time and can only be ascertained through appropriate discovery,
10 Plaintiff believes that there are at least hundreds or thousands of members in the
11 proposed Class. Millions of ACADIA shares were traded publicly during the Class
12 Period on the NASDAQ. As of January 31, 2018, ACADIA had 124,701,944 shares
13 of common stock outstanding. Record owners and other members of the Class may
14 be identified from records maintained by ACADIA or its transfer agent and may be
15 notified of the pendency of this action by mail, using the form of notice similar to
16 that customarily used in securities class actions.
17

18 57. Plaintiff's claims are typical of the claims of the members of the Class
19 as all members of the Class are similarly affected by Defendants' wrongful conduct
20 in violation of federal law that is complained of herein.
21

22 58. Plaintiff will fairly and adequately protect the interests of the members
23 of the Class and has retained counsel competent and experienced in class and
24 securities litigation.
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1 purchased or otherwise acquired ACADIA's securities relying upon the integrity of
2 the market price of the Company's securities and market information relating to
3 ACADIA, and have been damaged thereby.
4

5 62. During the Class Period, Defendants materially misled the investing
6 public, thereby inflating the price of ACADIA's securities, by publicly issuing false
7 and/or misleading statements and/or omitting to disclose material facts necessary to
8 make Defendants' statements, as set forth herein, not false and/or misleading. The
9 statements and omissions were materially false and/or misleading because they
10 failed to disclose material adverse information and/or misrepresented the truth about
11 ACADIA's business, operations, and prospects as alleged herein.
12
13

14 63. At all relevant times, the material misrepresentations and omissions
15 particularized in this Complaint directly or proximately caused or were a substantial
16 contributing cause of the damages sustained by Plaintiff and other members of the
17 Class. As described herein, during the Class Period, Defendants made or caused to
18 be made a series of materially false and/or misleading statements about ACADIA's
19 financial well-being and prospects. These material misstatements and/or omissions
20 had the cause and effect of creating in the market an unrealistically positive
21 assessment of the Company and its financial well-being and prospects, thus causing
22 the Company's securities to be overvalued and artificially inflated at all relevant
23 times. Defendants' materially false and/or misleading statements during the Class
24 Period resulted in Plaintiff and other members of the Class purchasing the
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1 Company's securities at artificially inflated prices, thus causing the damages
2 complained of herein when the truth was revealed.

3
4 **LOSS CAUSATION**

5 64. Defendants' wrongful conduct, as alleged herein, directly and
6 proximately caused the economic loss suffered by Plaintiff and the Class.

7
8 65. During the Class Period, Plaintiff and the Class purchased ACADIA's
9 securities at artificially inflated prices and were damaged thereby. The price of the
10 Company's securities significantly declined when the misrepresentations made to
11 the market, and/or the information alleged herein to have been concealed from the
12 market, and/or the effects thereof, were revealed, causing investors' losses.

13
14 **SCIENTER ALLEGATIONS**

15
16 66. As alleged herein, Defendants acted with scienter since Defendants
17 knew that the public documents and statements issued or disseminated in the name
18 of the Company were materially false and/or misleading; knew that such statements
19 or documents would be issued or disseminated to the investing public; and
20 knowingly and substantially participated or acquiesced in the issuance or
21 dissemination of such statements or documents as primary violations of the federal
22 securities laws. As set forth elsewhere herein in detail, the Individual Defendants,
23 by virtue of their receipt of information reflecting the true facts regarding ACADIA,
24 their control over, and/or receipt and/or modification of ACADIA's allegedly
25 materially misleading misstatements and/or their associations with the Company
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1 which made them privy to confidential proprietary information concerning
2 ACADIA, participated in the fraudulent scheme alleged herein.

3
4 **APPLICABILITY OF PRESUMPTION OF RELIANCE**
5 **(FRAUD-ON-THE-MARKET DOCTRINE)**

6 67. The market for ACADIA's securities was open, well-developed and
7 efficient at all relevant times. As a result of the materially false and/or misleading
8 statements and/or failures to disclose, ACADIA's securities traded at artificially
9 inflated prices during the Class Period. On June 8, 2016, the Company's stock price
10 closed at a Class Period high of \$41.55 per share. Plaintiff and other members of
11 the Class purchased or otherwise acquired the Company's securities relying upon
12 the integrity of the market price of ACADIA's securities and market information
13 relating to ACADIA, and have been damaged thereby.
14
15

16 68. During the Class Period, the artificial inflation of ACADIA's stock was
17 caused by the material misrepresentations and/or omissions particularized in this
18 Complaint causing the damages sustained by Plaintiff and other members of the
19 Class. As described herein, during the Class Period, Defendants made or caused to
20 be made a series of materially false and/or misleading statements about ACADIA's
21 business, prospects, and operations. These material misstatements and/or omissions
22 created an unrealistically positive assessment of ACADIA and its business,
23 operations, and prospects, thus causing the price of the Company's securities to be
24 artificially inflated at all relevant times, and when disclosed, negatively affected the
25 value of the Company stock. Defendants' materially false and/or misleading
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1 statements during the Class Period resulted in Plaintiff and other members of the
2 Class purchasing the Company's securities at such artificially inflated prices, and
3 each of them has been damaged as a result.
4

5 69. At all relevant times, the market for ACADIA's securities was an
6 efficient market for the following reasons, among others:
7

8 (a) ACADIA stock met the requirements for listing, and was listed and
9 actively traded on the NASDAQ, a highly efficient and automated market;
10

11 (b) As a regulated issuer, ACADIA filed periodic public reports with the
12 SEC and/or the NASDAQ;

13 (c) ACADIA regularly communicated with public investors via established
14 market communication mechanisms, including through regular dissemination of
15 press releases on the national circuits of major newswire services and through other
16 wide-ranging public disclosures, such as communications with the financial press
17 and other similar reporting services; and/or
18

19 (d) ACADIA was followed by securities analysts employed by brokerage
20 firms who wrote reports about the Company, and these reports were distributed to
21 the sales force and certain customers of their respective brokerage firms. Each of
22 these reports was publicly available and entered the public marketplace.
23
24

25 70. As a result of the foregoing, the market for ACADIA's securities
26 promptly digested current information regarding ACADIA from all publicly
27 available sources and reflected such information in ACADIA's stock price. Under
28

1 these circumstances, all purchasers of ACADIA’s securities during the Class Period
2 suffered similar injury through their purchase of ACADIA’s securities at artificially
3 inflated prices and a presumption of reliance applies.
4

5 71. A Class-wide presumption of reliance is also appropriate in this action
6 under the Supreme Court’s holding in *Affiliated Ute Citizens of Utah v. United*
7 *States*, 406 U.S. 128 (1972), because the Class’s claims are, in large part, grounded
8 on Defendants’ material misstatements and/or omissions. Because this action
9 involves Defendants’ failure to disclose material adverse information regarding the
10 Company’s business operations and financial prospects—information that
11 Defendants were obligated to disclose—positive proof of reliance is not a
12 prerequisite to recovery. All that is necessary is that the facts withheld be material
13 in the sense that a reasonable investor might have considered them important in
14 making investment decisions. Given the importance of the Class Period material
15 misstatements and omissions set forth above, that requirement is satisfied here.
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20 **NO SAFE HARBOR**

21 72. The statutory safe harbor provided for forward-looking statements
22 under certain circumstances does not apply to any of the allegedly false statements
23 pleaded in this Complaint. The statements alleged to be false and misleading herein
24 all relate to then-existing facts and conditions. In addition, to the extent certain of
25 the statements alleged to be false may be characterized as forward looking, they
26 were not identified as “forward-looking statements” when made and there were no
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1 meaningful cautionary statements identifying important factors that could cause
2 actual results to differ materially from those in the purportedly forward-looking
3 statements. In the alternative, to the extent that the statutory safe harbor is
4 determined to apply to any forward-looking statements pleaded herein, Defendants
5 are liable for those false forward-looking statements because at the time each of
6 those forward-looking statements was made, the speaker had actual knowledge that
7 the forward-looking statement was materially false or misleading, and/or the
8 forward-looking statement was authorized or approved by an executive officer of
9 ACADIA who knew that the statement was false when made.
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14 **FIRST CLAIM**
15 **Violation of Section 10(b) of The Exchange Act and**
16 **Rule 10b-5 Promulgated Thereunder**
17 **Against All Defendants**

18 73. Plaintiff repeats and re-alleges each and every allegation contained
19 above as if fully set forth herein.
20

21 74. During the Class Period, Defendants carried out a plan, scheme and
22 course of conduct which was intended to and, throughout the Class Period, did: (i)
23 deceive the investing public, including Plaintiff and other Class members, as alleged
24 herein; and (ii) cause Plaintiff and other members of the Class to purchase
25 ACADIA's securities at artificially inflated prices. In furtherance of this unlawful
26 scheme, plan and course of conduct, Defendants, and each defendant, took the
27 actions set forth herein.
28

75. Defendants (i) employed devices, schemes, and artifices to defraud; (ii)

1 made untrue statements of material fact and/or omitted to state material facts
2 necessary to make the statements not misleading; and (iii) engaged in acts, practices,
3
4 and a course of business which operated as a fraud and deceit upon the purchasers of
5 the Company's securities in an effort to maintain artificially high market prices for
6 ACADIA's securities in violation of Section 10(b) of the Exchange Act and Rule
7
8 10b-5. All Defendants are sued either as primary participants in the wrongful and
9 illegal conduct charged herein or as controlling persons as alleged below.

10 76. Defendants, individually and in concert, directly and indirectly, by the
11 use, means or instrumentalities of interstate commerce and/or of the mails, engaged
12 and participated in a continuous course of conduct to conceal adverse material
13 information about ACADIA's financial well-being and prospects, as specified
14 herein.
15
16

17 77. Defendants employed devices, schemes and artifices to defraud, while
18 in possession of material adverse non-public information and engaged in acts,
19 practices, and a course of conduct as alleged herein in an effort to assure investors of
20 ACADIA's value and performance and continued substantial growth, which
21 included the making of, or the participation in the making of, untrue statements of
22 material facts and/or omitting to state material facts necessary in order to make the
23 statements made about ACADIA and its business operations and future prospects in
24 light of the circumstances under which they were made, not misleading, as set forth
25 more particularly herein, and engaged in transactions, practices and a course of
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1 business which operated as a fraud and deceit upon the purchasers of the Company's
2 securities during the Class Period.

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4 78. Each of the Individual Defendants' primary liability and controlling
5 person liability arises from the following facts: (i) the Individual Defendants were
6 high-level executives and/or directors at the Company during the Class Period and
7 members of the Company's management team or had control thereof; (ii) each of
8 these defendants, by virtue of their responsibilities and activities as a senior officer
9 and/or director of the Company, was privy to and participated in the creation,
10 development and reporting of the Company's internal budgets, plans, projections
11 and/or reports; (iii) each of these defendants enjoyed significant personal contact
12 and familiarity with the other defendants and was advised of, and had access to,
13 other members of the Company's management team, internal reports and other data
14 and information about the Company's finances, operations, and sales at all relevant
15 times; and (iv) each of these defendants was aware of the Company's dissemination
16 of information to the investing public which they knew and/or recklessly
17 disregarded was materially false and misleading.

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22 79. Defendants had actual knowledge of the misrepresentations and/or
23 omissions of material facts set forth herein, or acted with reckless disregard for the
24 truth in that they failed to ascertain and to disclose such facts, even though such
25 facts were available to them. Such defendants' material misrepresentations and/or
26 omissions were done knowingly or recklessly and for the purpose and effect of
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1 concealing ACADIA's financial well-being and prospects from the investing public
2 and supporting the artificially inflated price of its securities. As demonstrated by
3
4 Defendants' overstatements and/or misstatements of the Company's business,
5 operations, financial well-being, and prospects throughout the Class Period,
6 Defendants, if they did not have actual knowledge of the misrepresentations and/or
7
8 omissions alleged, were reckless in failing to obtain such knowledge by deliberately
9 refraining from taking those steps necessary to discover whether those statements
10 were false or misleading.

11
12 80. As a result of the dissemination of the materially false and/or
13 misleading information and/or failure to disclose material facts, as set forth above,
14 the market price of ACADIA's securities was artificially inflated during the Class
15 Period. In ignorance of the fact that market prices of the Company's securities were
16 artificially inflated, and relying directly or indirectly on the false and misleading
17 statements made by Defendants, or upon the integrity of the market in which the
18 securities trades, and/or in the absence of material adverse information that was
19 known to or recklessly disregarded by Defendants, but not disclosed in public
20 statements by Defendants during the Class Period, Plaintiff and the other members
21 of the Class acquired ACADIA's securities during the Class Period at artificially
22 high prices and were damaged thereby.

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26 81. At the time of said misrepresentations and/or omissions, Plaintiff and
27 other members of the Class were ignorant of their falsity, and believed them to be
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1 true. Had Plaintiff and the other members of the Class and the marketplace known
2 the truth regarding the problems that ACADIA was experiencing, which were not
3 disclosed by Defendants, Plaintiff and other members of the Class would not have
4 purchased or otherwise acquired their ACADIA securities, or, if they had acquired
5 such securities during the Class Period, they would not have done so at the
6 artificially inflated prices which they paid.
7
8

9 82. By virtue of the foregoing, Defendants violated Section 10(b) of the
10 Exchange Act and Rule 10b-5 promulgated thereunder.
11

12 83. As a direct and proximate result of Defendants' wrongful conduct,
13 Plaintiff and the other members of the Class suffered damages in connection with
14 their respective purchases and sales of the Company's securities during the Class
15 Period.
16

17 **SECOND CLAIM**
18 **Violation of Section 20(a) of The Exchange Act**
19 **Against the Individual Defendants**

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

22 85. Individual Defendants acted as controlling persons of ACADIA within
23 the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of
24 their high-level positions and their ownership and contractual rights, participation in,
25 and/or awareness of the Company's operations and intimate knowledge of the false
26 financial statements filed by the Company with the SEC and disseminated to the
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1 investing public, Individual Defendants had the power to influence and control and
2 did influence and control, directly or indirectly, the decision-making of the
3 Company, including the content and dissemination of the various statements which
4 Plaintiff contends are false and misleading. Individual Defendants were provided
5 with or had unlimited access to copies of the Company's reports, press releases,
6 public filings, and other statements alleged by Plaintiff to be misleading prior to
7 and/or shortly after these statements were issued and had the ability to prevent the
8 issuance of the statements or cause the statements to be corrected.
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12 86. In particular, Individual Defendants had direct and supervisory
13 involvement in the day-to-day operations of the Company and, therefore, had the
14 power to control or influence the particular transactions giving rise to the securities
15 violations as alleged herein, and exercised the same.
16

17 87. As set forth above, ACADIA and Individual Defendants each violated
18 Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this
19 Complaint. By virtue of their position as controlling persons, Individual Defendants
20 are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate
21 result of Defendants' wrongful conduct, Plaintiff and other members of the Class
22 suffered damages in connection with their purchases of the Company's securities
23 during the Class Period.
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