

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 28, 2017

Commission File Number: 000-50768

**ACADIA Pharmaceuticals Inc.**

(Exact name of registrant as specified in its charter.)

Delaware

(State or other jurisdiction of incorporation or organization)

061376651

(IRS Employer Identification No.)

3611 Valley Centre Drive, Suite 300, San Diego, California 92130  
(Address of principal executive offices)

858-558-2871

(Registrant's Telephone number)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 2.02 Results of Operations and Financial Condition.**

On February 28, 2017, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2016. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rules and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

**Item 9.01 Financial Statements and Exhibits.**

(d) The following exhibit is furnished herewith:

99.1 Press release dated February 28, 2017

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ACADIA Pharmaceuticals Inc.**

Date: *February 28, 2017*

By: */s/ Glenn F. Baity*

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*Name: Glenn F. Baity*

*Title: EVP, General Counsel & Secretary*

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
EX-99.1	Press release dated February 28, 2017

## ACADIA Pharmaceuticals Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2016

*NUPLAZID® Net Product Sales Grew to \$12.0 Million in Fourth Quarter 2016*

*Executing on Broad Clinical Development Program in Alzheimer's Disease Psychosis, Alzheimer's Disease Agitation, Schizophrenia Inadequate Response, Negative Symptoms of Schizophrenia, and Major Depressive Disorder*

**SAN DIEGO, CA February 28, 2017** – 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 for the fourth quarter and year ended December 31, 2016.

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

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

### Recent Highlights

- NUPLAZID now available on Medicare formularies for the treatment of Parkinson's disease psychosis (PD Psychosis); commercial coverage decisions now made for over 60% of 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.
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## Financial Results

### *Revenue*

ACADIA reported net product sales of \$12.0 million for the fourth quarter of 2016. NUPLAZID was launched commercially in May 2016, so there were no similar product sales for the comparable quarter of 2015. Through ACADIA's NUPLAZIDconnect™ site, upon initiation of therapy, physicians have been able to prescribe patients a 30-day free trial of NUPLAZID for which no revenue is recognized.

### *Research and Development*

Research and development expenses increased to \$30.2 million for the fourth quarter of 2016 from \$20.5 million for the comparable quarter of 2015. This increase was primarily due to increased clinical costs related to the development of pimavanserin in indications other than PD Psychosis and an increase in personnel and related costs associated with ACADIA's expanded research and development organization.

### *Selling, General and Administrative*

Selling, general and administrative expenses increased to \$57.7 million for the fourth quarter of 2016 from \$22.6 million for the comparable quarter of 2015. This increase was primarily due to costs related to the hiring of our specialty sales force in April 2016 and costs incurred to support our commercial activities for NUPLAZID.

### *Net Loss*

For the fourth quarter of 2016, ACADIA reported a net loss of \$78.7 million, or \$0.65 per common share, compared to a net loss of \$45.8 million, or \$0.45 per common share, for the comparable quarter of 2015. The net losses for the fourth quarters of 2016 and 2015 included \$15.4 million and \$8.9 million, respectively, of non-cash stock-based compensation expense. For the year ended December 31, 2016, ACADIA reported a net loss of \$271.4 million, or \$2.34 per common share, compared to a net loss of \$164.4 million, or \$1.63 per common share, for 2015. The net losses for the years ended December 31, 2016 and 2015 included \$55.3 million and \$40.2 million, respectively, of non-cash stock-based compensation expense.

### *Cash and Investments*

At December 31, 2016, ACADIA's cash, cash equivalents and investment securities totaled \$529.0 million, compared to \$215.1 million at December 31, 2015.

### *Conference Call and Webcast Information*

ACADIA management will review its fourth quarter financial results and operations via conference call and webcast later today at 5:00 p.m. Eastern Time. The conference call may be accessed by dialing 844-821-1109 for participants in the U.S. or Canada and 830-865-2550 for international callers (reference passcode 74539512). A telephone replay of the conference call may be accessed through March 14, 2017 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 74539512). The conference call also will be webcast live on ACADIA's website, [www.acadia-pharm.com](http://www.acadia-pharm.com), under the investors section and will be archived there until March 14, 2017.

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*About NUPLAZID® (pimavanserin)*

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with PD Psychosis. NUPLAZID is a non-dopaminergic, selective serotonin inverse agonist preferentially targeting 5-HT<sub>2A</sub> receptors that are thought to play an important role in PD Psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg (two 17-mg tablets). ACADIA discovered this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

*About ACADIA Pharmaceuticals*

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA maintains a website at [www.acadia-pharm.com](http://www.acadia-pharm.com) to which we regularly post copies of our press releases as well as additional information and through which interested parties can subscribe to receive e-mail alerts.

*Forward-Looking Statements*

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements related to the benefits to be derived from NUPLAZID (pimavanserin); the potential of pimavanserin to improve the lives of patients across multiple CNS disease states and our commitment to explore this potential in broad and substantive clinical programs; and the utility of pimavanserin in indications other than hallucinations and delusions associated with PD Psychosis. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug discovery, development, and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2016 as well as ACADIA's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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**ACADIA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)  
(Unaudited)

	<b>Three Months Ended</b>		<b>Years Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Revenues</b>				
Product sales, net	\$ 11,962	\$ —	\$ 17,327	\$ —
Collaborative revenues	—	17	4	61
<b>Total revenues</b>	<b>11,962</b>	<b>17</b>	<b>17,331</b>	<b>61</b>
<b>Operating expenses</b>				
Cost of product sales	1,704	—	3,075	—
License fees and royalties	608	2,500	1,331	2,500
Research and development	30,218	20,466	99,284	73,869
Selling, general and administrative	57,663	22,616	186,456	88,304
<b>Total operating expenses</b>	<b>90,193</b>	<b>45,582</b>	<b>290,146</b>	<b>164,673</b>
<b>Loss from operations</b>	<b>(78,231)</b>	<b>(45,565)</b>	<b>(272,815)</b>	<b>(164,612)</b>
Interest income, net	876	111	2,763	499
<b>Loss before income taxes</b>	<b>(77,355)</b>	<b>(45,454)</b>	<b>(270,052)</b>	<b>(164,113)</b>
Income tax expense	1,341	330	1,341	330
<b>Net loss</b>	<b>\$ (78,696)</b>	<b>\$ (45,784)</b>	<b>\$ (271,393)</b>	<b>\$ (164,443)</b>
Net loss per common share, basic and diluted	\$ (0.65)	\$ (0.45)	\$ (2.34)	\$ (1.63)
Weighted average common shares outstanding, basic and diluted	121,202	101,207	115,858	100,630



**ACADIA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)  
(Unaudited)

	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Assets</b>		
Cash, cash equivalents, and investment securities	\$ 529,036	\$ 215,132
Accounts receivable, net	5,903	—
Interest and other receivables	1,237	1,638
Inventory	4,175	—
Prepaid expenses and other current assets	7,546	2,219
Total current assets	547,897	218,989
Property and equipment, net	3,081	2,203
Intangible assets, net	7,015	—
Restricted cash	2,375	375
Other assets	785	329
Total assets	<u>\$ 561,153</u>	<u>\$ 221,896</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 3,912	\$ 1,672
Accrued liabilities	36,029	20,230
Deferred revenue	2,644	—
Total current liabilities	42,585	21,902
Long-term liabilities	157	232
Total liabilities	42,742	22,134
Total stockholders' equity	518,411	199,762
Total liabilities and stockholders' equity	<u>\$ 561,153</u>	<u>\$ 221,896</u>

**Important Safety Information and Indication for NUPLAZID (pimavanserin) tablets**

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. 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.**

NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

**QT Interval Prolongation:** NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics. NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

**Adverse Reactions:** The most common adverse reactions ( $\geq 2\%$  for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

**Drug Interactions:** Strong CYP3A4 inhibitors (eg, ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half. Strong CYP3A4 inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

**Renal Impairment:** No dosage adjustment for NUPLAZID is needed in patients with mild to moderate renal impairment. Use of NUPLAZID is not recommended in patients with severe renal impairment.

**Hepatic Impairment:** Use of NUPLAZID is not recommended in patients with hepatic impairment. NUPLAZID has not been evaluated in this patient population.

**Pregnancy:** Use of NUPLAZID in pregnant women has not been evaluated and should therefore be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

**Pediatric Use:** Safety and efficacy have not been established in pediatric patients.

**Dosage and Administration:** Recommended dose: 34 mg per day, taken orally as two 17-mg tablets once daily, without titration.

For additional Important Safety Information, including boxed warning, please see the full Prescribing Information for NUPLAZID at [https://www.nuplazid.com/pdf/NUPLAZID\\_Prescribing\\_Information.pdf](https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf).

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