

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): November 7, 2016

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 November 7, 2016, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the third quarter and nine months ended September 30, 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 November 7, 2016.

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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: *November 7, 2016*

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 November 7, 2016

**ACADIA Pharmaceuticals Reports  
Third Quarter 2016 Financial Results**

*NUPLAZID® Net Product Sales Grew to \$5.3 Million in the First Full Quarter of Commercialization*

*Expanding Pimavanserin Clinical Program With Initiation of Studies for Alzheimer's Disease Agitation and Adjunctive Treatment of Schizophrenia*

**SAN DIEGO, CA November 7, 2016** – 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 unaudited financial results for the third quarter ended September 30, 2016.

“We are very pleased with the launch and are gratified by the positive feedback we have received from physicians, patients, and caregivers on NUPLAZID (pimavanserin),” said Steve Davis, ACADIA’s President and Chief Executive Officer. “We saw solid month-over-month prescription growth, reported increased payor coverage, and continued 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.”

**Recent Highlights**

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

### *Revenue*

ACADIA reported net product sales of \$5.3 million for the three months ended September 30, 2016. No similar net product sales were reported for the comparable period of 2015. NUPLAZID was made available for prescription starting May 31, 2016. Through ACADIA's NUPLAZIDconnect™ site, upon initiation of therapy, physicians are 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 \$25.8 million for the three months ended September 30, 2016 from \$18.7 million for the comparable period of 2015. This increase was primarily due to increased clinical costs related to the development of pimavanserin in indications other than Parkinson's disease 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 \$50.5 million for the three months ended September 30, 2016 from \$20.3 million for the comparable period 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 three and nine months ended September 30, 2016, ACADIA reported a net loss of \$71.6 million and \$192.7 million, or \$0.61 and \$1.69 per common share, respectively, compared to a net loss of \$38.9 million and \$118.7 million, or \$0.39 and \$1.18 per common share, for the comparable periods of 2015, respectively. The net losses for the three and nine months ended September 30, 2016 included \$14.0 million and \$39.8 million, respectively, of non-cash stock-based compensation expense compared to \$9.3 million and \$31.3 million for the comparable periods of 2015, respectively.

### *Cash and Investments*

At September 30, 2016, ACADIA's cash, cash equivalents and investment securities totaled \$588.9 million, compared to \$215.1 million at December 31, 2015.

### *Conference Call and Webcast Information*

ACADIA management will review its third 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 6571523). A telephone replay of the conference call may be accessed through November 21, 2016 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 6571523). 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 November 21, 2016.

### *About NUPLAZID® (pimavanserin)*

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease 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 Parkinson's disease 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.

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## *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 focus of commercial initiatives, the ability to improve the lives of patients with CNS disorders, and the expected timing of the announcement of top-line results from ACADIA's Phase II Alzheimer's disease psychosis study. 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, whether NUPLAZID receives adequate reimbursement from third-party payors, ACADIA's ability to establish and maintain an adequate specialty pharmacy network to distribute NUPLAZID, the degree to which NUPLAZID receives acceptance from patients and physicians for its approved indication, 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, 2015 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>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Revenues</b>				
Product sales, net	\$ 5,268	\$ —	\$ 5,365	\$ —
Collaborative revenues	—	39	4	44
Total revenues	<u>5,268</u>	<u>39</u>	<u>5,369</u>	<u>44</u>
<b>Operating expenses</b>				
Cost of product sales	845	—	1,371	—
License fees and royalties	475	—	723	—
Research and development	25,813	18,729	69,066	53,403
Selling, general and administrative	50,534	20,308	128,793	65,688
Total operating expenses	<u>77,667</u>	<u>39,037</u>	<u>199,953</u>	<u>119,091</u>
Loss from operations	(72,399)	(38,998)	(194,584)	(119,047)
Interest income, net	786	92	1,887	388
Net loss	<u>\$ (71,613)</u>	<u>\$ (38,906)</u>	<u>\$ (192,697)</u>	<u>\$ (118,659)</u>
Net loss per common share, basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.39)</u>	<u>\$ (1.69)</u>	<u>\$ (1.18)</u>
Weighted average common shares outstanding, basic and diluted	<u>117,497</u>	<u>100,756</u>	<u>114,063</u>	<u>100,436</u>



**ACADIA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	<b>September 30,</b>	<b>December 31,</b>
	<b>2016</b>	<b>2015</b>
	<u>(unaudited)</u>	
<b>Assets</b>		
Cash, cash equivalents, and investment securities	\$ 588,859	\$ 215,132
Accounts receivable, net	3,839	—
Interest and other receivables	1,385	1,638
Inventory	4,301	—
Prepaid expenses and other current assets	5,106	2,219
Total current assets	<u>603,490</u>	<u>218,989</u>
Property and equipment, net	3,159	2,203
Intangible assets, net	7,385	—
Restricted cash	2,375	375
Other assets	975	329
Total assets	<u>\$ 617,384</u>	<u>\$ 221,896</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 2,828	\$ 1,672
Accrued liabilities	34,445	20,230
Deferred revenue	1,876	—
Total current liabilities	<u>39,149</u>	<u>21,902</u>
Long-term liabilities	177	232
Total liabilities	<u>39,326</u>	<u>22,134</u>
Total stockholders' equity	578,058	199,762
Total liabilities and stockholders' equity	<u>\$ 617,384</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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