#### 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): May 5, 2016

Commission File Number: 000-50768

# **ACADIA Pharmaceuticals Inc.**

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

<u>Delaware</u> (State or other jurisdiction of incorporation or organization) <u>061376651</u> (IRS Employer Identification No.)

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

<u>858-558-2871</u>

(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))

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

On May 5, 2016, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the first quarter and three months ended March 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 May 5, 2016.

## 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: May 5, 2016

By: /s/ Glenn F. Baity

Name: Glenn F. Baity Title: EVP, General Counsel & Secretary

## Exhibit Index

# Exhibit No. Description

EX-99.1 Press Release dated May 5, 2016.

### ACADIA Pharmaceuticals Reports First Quarter 2016 Financial Results

SAN DIEGO, CA May 5, 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 disorders, today announced its unaudited financial results for the first quarter ended March 31, 2016.

"We are very excited about the recent FDA approval of NUPLAZID<sup>TM</sup>, the first and only drug approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis," said Steve Davis, ACADIA's President and Chief Executive Officer. "Parkinson's psychosis tends to strike in the more advanced stages of Parkinson's disease – at a time when patients are often experiencing significant challenges in controlling their motor symptoms such as tremor, slow movement and muscle rigidity. For the first time, physicians will have a drug to treat hallucinations and delusions without worsening motor function in Parkinson's psychosis patients. We look forward to making NUPLAZID available to physicians and patients in June."

ACADIA reported a net loss of \$49.8 million, or \$0.45 per common share, for the first quarter of 2016 compared to a net loss of \$40.4 million, or \$0.40 per common share, for the first quarter of 2015. The net losses for the first quarters of 2016 and 2015 included \$12.0 million and \$14.5 million, respectively, in non-cash stock-based compensation expense. At March 31, 2016, ACADIA's cash, cash equivalents and investment securities totaled \$457.2 million, compared to \$215.1 million at December 31, 2015.

Research and development expenses increased to \$22.8 million for the first quarter of 2016, including \$4.4 million in stock-based compensation expense, from \$16.3 million for the comparable quarter of 2015, including \$2.4 million in stock-based compensation expense. This increase was due to an increase in personnel and related costs of \$4.8 million associated with ACADIA's expanded research and development organization and an increase of \$1.7 million in external service costs. The increase in external service costs was primarily due to increased costs in connection with the FDA's Psychopharmacologic Drugs Advisory Committee meeting that occurred in March 2016 and increased costs related to the development of pimavanserin in additional indications other than in Parkinson's disease psychosis, largely offset by pimavanserin manufacturing development costs incurred in the first quarter of 2015 not incurred in the first quarter of 2016.

General and administrative expenses increased to \$27.5 million for the first quarter of 2016, including \$7.6 million in stock-based compensation expense, from \$24.3 million for the comparable quarter of 2015, including \$12.2 million in stock-based compensation expense. This increase was due to an increase of \$4.8 million in external service costs offset by a decrease of \$1.6 million in personnel and related costs and stock-based compensation expense. The decrease in personnel costs and stock-based compensation expense was driven by a one-time expense of \$9.6 million incurred in the first quarter of 2015 in connection with the retirement of ACADIA's former Chief Executive Officer, including \$9.0 million of stock-based compensation expense. Excluding these one-time costs, the increases in personnel costs and external service costs were largely related to ACADIA's commercial preparations for the upcoming launch of NUPLAZID.

### Conference Call and Webcast Information

ACADIA management will review its first 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 5151879). A telephone replay of the conference call may be accessed through May 19, 2016 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 5151879). The conference call also will be webcast live on ACADIA's website, <u>www.acadia-pharm.com</u>, under the investors section and will be archived there until May 19, 2016.

#### About NUPLAZID<sup>TM</sup> (pimavanserin)

NUPLAZID is the first FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a nondopaminergic, selective serotonin inverse agonist preferentially targeting 5-HT2A 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.

#### 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 <u>www.acadia-pharm.com</u> 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); and ACADIA's plans to make NUPLAZID commercially available in the United States, including the timing thereof. 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 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.

# ACADIA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts) (Unaudited)

	Three Months Ended March 31,			
	 2016		2015	
Revenues				
Collaborative revenues	\$ 4	\$	4	
Operating expenses				
Research and development	22,775		16,295	
General and administrative	 27,491		24,261	
Total operating expenses	50,266		40,556	
Loss from operations	(50,262)		(40,552)	
Interest income, net	500		177	
Net loss	\$ (49,762)	\$	(40,375)	
Net loss per common share, basic and diluted	\$ (0.45)	\$	(0.40)	
Weighted average common shares outstanding, basic and diluted	111,346	_	100,197	

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

	M	March 31, 2016		December 31, 2015	
Assets					
Cash, cash equivalents and investment securities	\$	457,243	\$	215,132	
Prepaid expenses, receivables and other current assets		5,109		3,857	
Total current assets		462,352		218,989	
Restricted cash		375		375	
Other non-current assets		3,863		2,532	
Total assets	\$	466,590	\$	221,896	
Liabilities and stockholders' equity					
Total liabilities	\$	21,339	\$	22,134	
Stockholders' equity		445,251		199,762	
Total liabilities and stockholders' equity	\$	466,590	\$	221,896	

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.

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.

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