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): August 4, 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)

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))

Item 2.02 Results of Operations and Financial Condition.

On August 4, 2016, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter and six months ended June 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 August 4, 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: August 4, 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 August 4, 2016.

ACADIA Pharmaceuticals Reports Second Quarter 2016 Financial Results

Quarter highlighted by approval and launch of NUPLAZID™ (pimavanserin) in the United States, the first and only FDA-approved drug for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis

SAN DIEGO, CA August 4, 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 second quarter ended June 30, 2016.

"The second quarter of 2016 was highlighted by transformative events for ACADIA, including the FDA approval and recent commercial launch of NUPLAZIDTM," said Steve Davis, ACADIA's President and Chief Executive Officer. "We are executing on our plans to bring NUPLAZID to patients in need – our sales specialists have been trained and deployed; our patient and physician support system, NUPLAZIDconnectTM, became operational at approval; we are expanding awareness of NUPLAZID among healthcare professionals through a number of initiatives including speaker programs, media and digital campaigns, and symposia at major medical meetings; and we are working with payors to make NUPLAZID available to eligible patients."

Recent Highlights

- NUPLAZID (pimavanserin) 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 (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.

Financial Results

Revenue

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

Research and Development

Research and development expenses increased to \$20.5 million for the three months ended June 30, 2016 from \$18.4 million for the comparable period of 2015. This increase was primarily due to increased personnel and related costs associated with ACADIA's expanded research and development organization, and increased clinical costs related to the development of pimavanserin in indications other than Parkinson's disease psychosis. These increases were partially offset by decreased manufacturing development costs.

Selling, General and Administrative

Selling, general and administrative expenses increased to \$50.8 million for the three months ended June 30, 2016 from \$21.1 million for the comparable period of 2015. This increase was primarily due to preparations for, and support of, the launch of NUPLAZID, and the hiring of our specialty sales force in April 2016, as well as additional medical education programs.

Net Loss

For the three and six months ended June 30, 2016, ACADIA reported a net loss of \$71.3 million and \$121.1 million, or \$0.63 and \$1.08 per common share, respectively, compared to a net loss of \$39.4 million and \$79.8 million, or \$0.39 and \$0.80 per common share, for the comparable periods of 2015, respectively. The net losses for the three and six months ended June 30, 2016 included \$13.9 million and \$25.8 million, respectively, of non-cash stock-based compensation expense compared to \$7.5 million and \$22.0 million for the comparable periods of 2015, respectively.

Cash and Investments

At June 30, 2016, ACADIA's cash, cash equivalents and investment securities totaled \$412.6 million, compared to \$215.1 million at December 31, 2015.

Conference Call and Webcast Information

ACADIA management will review its second 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 54186458). A telephone replay of the conference call may be accessed through August 18, 2016 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 54186458). The conference call also will be webcast live on ACADIA's website, www.acadia-pharm.com, under the investors section and will be archived there until August 18, 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 $5-HT_{2A}$ 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); the ability of ACADIA to work with payors to make NUPLAZID available to eligible patients, ACADIA's ability to expand awareness of NUPLAZID among physicians through a number of initiatives, timing regarding the commencement of clinical trials, including the planned Alzheimer's disease agitation study, 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 circums

ACADIA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended June 30,			Six Months Ended June 30,			
	 2016		2015	2016		2015	
Revenues							
Product sales, net	\$ 97	\$		\$ 97	\$		
Collaborative revenues	 		1	 4		5	
Total revenues	 97		1	 101		5	
Operating expenses							
Cost of product sales	526		_	526			
License fees and royalties	248		_	248		_	
Research and development	20,478		18,379	43,253		34,674	
Selling, general and administrative	50,768		21,119	78,259		45,380	
Total operating expenses	72,020		39,498	122,286		80,054	
Loss from operations	(71,923)		(39,497)	(122,185)		(80,049)	
Interest income, net	 601		119	 1,101		296	
Net loss	\$ (71,322)	\$	(39,378)	\$ (121,084)	\$	(79,753)	
Net loss per common share, basic and diluted	\$ (0.63)	\$	(0.39)	\$ (1.08)	\$	(0.80)	
Weighted average common shares outstanding, basic and diluted	 113,308		100,349	 112,327		100,273	

ACADIA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	•	June 30, 2016	December 31, 2015	
	(u	inaudited)		
Assets				
Cash and cash equivalents	\$	131,774 \$		
Investment securities, available-for-sale		280,781	112,994	
Accounts receivable, net		293	—	
Interest and other receivables		1,340	1,638	
Inventory		2,867	—	
Prepaid expenses and other current assets		6,842	2,219	
Total current assets		423,897	218,989	
Property and equipment, net		2,897	2,203	
Intangible assets, net		7,754	—	
Restricted cash		2,375	375	
Other assets		1,111	329	
Total assets	\$	438,034	\$ 221,896	
Liabilities and stockholders' equity				
Accounts payable	\$	1,024 \$	\$ 1,672	
Accrued liabilities		27,485	20,230	
Deferred revenue		513		
Total current liabilities		29,022	21,902	
Long-term liabilities		197	232	
Total liabilities		29,219	22,134	
Total stockholders' equity		408,815	199,762	
Total liabilities and stockholders' equity	\$	438,034	\$ 221,896	

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.

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