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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

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

**Date of report (Date of earliest event reported): April 27, 2016**

**Commission File Number: 000-50768**

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**ACADIA Pharmaceuticals Inc.**  
(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**061376651**  
(IRS Employer  
Identification No.)

**3611 Valley Centre Drive, #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)

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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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

**(b)**

On April 27, 2016, Leslie L. Iversen, Ph.D. and William M. Wells each notified us that he will not be standing for re-election as a member of our Board of Directors at our 2016 Annual Meeting of Stockholders, scheduled for June 10, 2016. Additionally, on April 27, 2016, Mary Ann Gray, Ph.D. notified us that she will be resigning as a member of our Board of Directors in connection with our 2016 Annual Meeting of Stockholders.

**Item 8.01 Other Events**

On April 29, 2016, we announced that the U.S. Food and Drug Administration, or FDA, has approved NUPLAZID (pimavanserin) for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PDP. The label for NUPLAZID also contains a "boxed" warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PDP. We plan to commence commercial sales of NUPLAZID in the United States in June 2016.

Additionally, in connection with the FDA approval of NUPLAZID, we have committed to conduct the following post-marketing studies: (i) a randomized, placebo-controlled withdrawal study in PDP patients treated with NUPLAZID, (ii) studies to collect additional data to add to the NUPLAZID safety database from an aggregate of at least 500 predominantly frail and elderly subjects on NUPLAZID in one or more randomized, placebo-controlled studies of eight or more weeks duration, (iii) a drug-drug interaction study with NUPLAZID and a strong CYP3A4 inducer and (iv) re-analysis of tissue samples from certain previously conducted pre-clinical studies. The clinical commitments we have agreed to are consistent with our overall life-cycle management plans. For example, data from our ongoing study in Alzheimer's disease psychosis and our planned study in Alzheimer's disease agitation will contribute to the commitment to gather additional safety data in predominantly frail and elderly patients.

On April 29, 2016, we issued a press release announcing the approval of NUPLAZID, a copy of which is attached as Exhibit 99.1 to this report.

*Forward-Looking Statements*

Statements in this report that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements related to our plans to commence commercial sales of NUPLAZID in the United States; our plans to conduct post-marketing studies; contributions to our safety database for NUPLAZID from our ongoing Alzheimer's disease psychosis and our planned study in Alzheimer's disease agitation; and our overall life-cycle management plans, including our planned study in Alzheimer's disease agitation. 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 payers, our 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 studies may not be indicative of future study results. For a discussion of these and other factors, please refer to our annual report on Form 10-K for the year ended December 31, 2015 as well as our 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 we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 29, 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.

Date: May 3, 2016

**ACADIA Pharmaceuticals Inc.**

By: /s/ Glenn F. Baity

Name: Glenn F. Baity

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Title: EVP, General Counsel & Secretary

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 29, 2016.



**FDA Approves ACADIA Pharmaceuticals' NUPLAZID™ (pimavanserin) -  
The First Drug Approved for the Treatment of Hallucinations and Delusions Associated  
with Parkinson's Disease Psychosis**

*U.S. Commercial Launch Planned for June 2016*

*An Estimated 40 Percent of Parkinson's Disease Patients Have Psychosis*

*Conference Call Scheduled on Monday, May 2 at 8:30 a.m. ET*

**SAN DIEGO – April 29, 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 that the U.S. Food and Drug Administration (FDA) has approved NUPLAZID (pimavanserin) for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. In 2014, the FDA designated NUPLAZID as a Breakthrough Therapy for this condition.

"Today's approval of NUPLAZID represents a major paradigm shift in the treatment of Parkinson's disease psychosis," said Michael S. Okun, M.D., Medical Director of The National Parkinson Foundation. "Through its novel and selective mechanism of action, NUPLAZID is a breakthrough treatment that works in a whole new way - treating hallucinations and delusions without blocking dopamine receptors and, therefore, not impairing motor function in Parkinson's psychosis patients."

NUPLAZID is the first and only medicine to be approved by the FDA for this indication. NUPLAZID is also the only drug approved by the FDA that preferentially targets 5-HT<sub>2A</sub> 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<sub>2A</sub> 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.

According to the National Parkinson Foundation, about one million people in the United States and from four to six million people worldwide suffer from Parkinson's disease. An estimated 40 percent of these patients have Parkinson's disease psychosis, which is characterized by hallucinations and delusions, is associated with significant caregiver burden, and is a major reason for nursing home placement among Parkinson's patients.

"NUPLAZID represents a major medical advancement for patients with Parkinson's disease psychosis who suffer from hallucinations and delusions," said Steve Davis, ACADIA's President and Chief Executive Officer. "We are grateful to the many patients and investigators who participated in NUPLAZID's clinical studies. NUPLAZID represents the culmination of many years of work across our entire organization to bring this novel medicine, discovered by our scientists, to patients in need."

"Parkinson's disease psychosis is a debilitating condition that adds a tremendous burden on the lives of patients already contending with motor issues such as slow movement, loss of balance, and muscle rigidity," said Todd Sherer, Ph.D., Chief Executive Officer of the Michael J. Fox Foundation. "It also places an increased burden on caregivers and can lead to loss of independence and nursing home admittance for patients. A therapy to treat the hallucinations and delusions associated with Parkinson's disease psychosis without worsening motor symptoms can significantly impact the lives of Parkinson's patients and their loved ones."

### ***Clinical Data***

The FDA approval of NUPLAZID was based on data from the pivotal Phase III Study -020 and other supportive studies, representing the largest research and development program in Parkinson's disease psychosis to date. In Study -020, NUPLAZID significantly reduced the

frequency and severity of psychotic symptoms compared to placebo on the Scale for Assessment of Positive Symptoms – Parkinson’s Disease (SAPS-PD). This benefit was achieved without impairing motor function. The most common adverse reactions (35% and twice the rate of placebo) in this study were peripheral edema (7% NUPLAZID vs 3% placebo) and confusional state (6% NUPLAZID vs 3% placebo). Results of Study -020 were published in The Lancet. Please see full prescribing information at [www.nuplazid.com](http://www.nuplazid.com).

### **Introducing NUPLAZIDconnect™ Patient Access and Support Services**

ACADIA plans to make NUPLAZID commercially available to patients suffering from hallucinations and delusions associated with Parkinson’s disease psychosis in the United States in June 2016. ACADIA is committed to ensuring that patients in the United States who are prescribed NUPLAZID are able to access the medicine and receive the ongoing support they may need. ACADIA will be introducing NUPLAZIDconnect, a comprehensive program that provides financial assistance and/or access assistance to patients, their caregivers, and physicians. NUPLAZID will be available through a specialty pharmacy network. Patients and physicians can access information about NUPLAZID and NUPLAZIDconnect by visiting [www.nuplazid.com](http://www.nuplazid.com) or calling 844-737-2223.

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

<p><b>WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS</b> <b>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.</b></p>
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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 (≥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.

### ***Conference Call***

ACADIA will hold a conference call and webcast on Monday, May 2, 2016 at 8:30 a.m. ET to discuss the FDA approval of NUPLAZID. 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 3844233). A telephone replay of the conference call may be accessed through May 16, 2016 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 3844233). 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 May 16, 2016.



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***About NUPLAZID™ (pimavanserin)***

NUPLAZID is the first 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.

***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 ACADIA's product candidates, including NUPLAZID (pimavanserin); whether NUPLAZID represents a paradigm shift in the treatment of Parkinson's disease psychosis (PDP) patients; whether NUPLAZID is a breakthrough treatment that works in a whole new way; whether NUPLAZID establishes a new class of drug; whether NUPLAZID represents a major medical advancement for PDP patients who suffer from hallucinations and delusions; whether a therapy to treat the hallucinations and delusions associated with PDP without worsening motor symptoms can significantly impact the lives of Parkinson's patients and their loved ones; ACADIA's plans to make NUPLAZID commercially available in the United States, including the timing thereof; whether ACADIA will be able to ensure patients have access to NUPLAZID; and the assistance that will be available to patients, their caregivers and physicians from ACADIA,

including through NUPLAZIDconnect. 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 payers, 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.

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