ACADIA PHARMACEUTICALS INC
Form 8-K
May 03, 2016

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): April 27, 2016

Commission File Number: 000-50768

ACADIA Pharmaceuticals Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**061376651**
(State or other jurisdiction of incorporation or organization)	**(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)

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 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

Exhibit No.	Description
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
Title: EVP, General Counsel & Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 29, 2016.