ACADIA PHARMACEUTICALS INC
Form 8-K
December 20, 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): December 20, 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))

Item 8.01 Other Events.

On December 20, 2016, ACADIA Pharmaceuticals Inc. announced positive top-line results from its Phase II exploratory study of pimavanserin in patients with Alzheimer's disease psychosis, or AD Psychosis. In this Phase II exploratory study, referred to as the -019 study, pimavanserin met the primary endpoint showing a statistically significant reduction in psychosis versus placebo as measured by the Neuropsychiatric Inventory-Nursing Home (NPI-NH) Psychosis score at week six of dosing (p=0.0451). A copy of ACADIA's press release related to the top-line results is attached as Exhibit 99.1.

Trial Design and Top-line Results

The Phase II -019 study was a double-blind, placebo-controlled exploratory trial designed to evaluate the efficacy and safety of pimavanserin as a treatment for patients with AD Psychosis. A total of 181 patients were enrolled in the study in the United Kingdom and randomized on a one-to-one basis to receive either 34 mg of pimavanserin or placebo once daily. The primary endpoint of the study was antipsychotic efficacy as measured by the mean change in the NPI-NH Psychosis score (combined hallucinations and delusions domains) from baseline to week six of dosing. Patients continued dosing through week 12 to gather information on secondary endpoints, including changes in cognition.

Pimavanserin demonstrated efficacy on the primary endpoint of the -019 study with a 3.76 point improvement in psychosis at week 6 compared to a 1.93 point improvement for placebo, representing a statistically significant treatment improvement in the NPI-NH Psychosis score (p=0.0451). Baseline mean scores for the pimavanserin and placebo treated groups were 9.52 and 10.00, respectively. In the -019 study, over the course of 12 weeks of treatment, pimavanserin did not impair cognition as measured by the Mini Mental State Examination (MMSE) score and was similar to placebo. On the secondary endpoint of mean change in NPI-NH Psychosis score at week 12, pimavanserin maintained the improvement on psychosis observed at the week six primary endpoint, but did not statistically separate from placebo.

Safety and Tolerability

In the -019 study, pimavanserin was generally well tolerated and the safety profile was consistent with what has been observed in previous studies. Based on a preliminary analysis of safety data, the most common adverse events reported in the -019 study were falls, urinary tract infection and agitation. The mortality rate in the -019 study was the same in the pimavanserin and placebo treatment groups. The mean age of patients in the study was 86 years.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished herewith:

99.1 Press release dated December 20, 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: *December 20, 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 December 20, 2016