ACADIA PHARMACEUTICALS INC
Form 8-K
April 11, 2013

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 11, 2013

Commission File Number: 000-50768

ACADIA Pharmaceuticals Inc.
(Exact name of small business issuer as specified in its charter)

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

3911 Sorrento Valley Blvd, San Diego, California 92121
(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 April 11, 2013, ACADIA Pharmaceuticals Inc. announced that the U.S. Food and Drug Administration, or FDA, had agreed that the data from ACADIA's pivotal Phase III -020 study, together with supportive data from other studies with pimavanserin, are sufficient to support the filing of a New Drug Application, or NDA, for the treatment of Parkinson's disease psychosis, or PDP. As a result, ACADIA also announced that it will no longer conduct the Phase III -021 study that was planned as a confirmatory trial and was scheduled to be initiated later in April.

ACADIA announced that it is currently focused on completing the remaining elements of its pimavanserin PDP development program that are needed for submission of an NDA. These include customary supportive studies, such as drug-drug interaction studies, and Chemistry, Manufacturing and Controls, or CMC, development, such as stability testing of registration batches. Subject to changes that could result from future interactions with the FDA or other developments, ACADIA is currently targeting an NDA submission near the end of 2014. While the FDA has agreed to accept and review an NDA for pimavanserin on the basis of ACADIA's positive pivotal -020 study, along with supportive efficacy and safety data from other pimavanserin studies, the NDA will be subject to a standard FDA review to determine whether the filing package is adequate to support approval of pimavanserin for PDP.

The press release announced that ACADIA will hold a conference call and webcast today at 8:00 a.m. Eastern time to discuss the foregoing.

This report contains 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 the potential benefit of pimavanserin to PDP sufferers, ACADIA's future activities in the pimavanserin program, ACADIA's expected timing of submitting an NDA for pimavanserin, and future acceptance for filing of a pimavanserin NDA by the FDA. 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, any future failure to reach agreement with the FDA on the regulatory path for pimavanserin for PDP, any issues that may arise related to the planned supportive studies or CMC development related to pimavanserin, and the risk that an NDA for pimavanserin is not accepted or ultimately approved by the FDA. 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, 2012 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 report to reflect events or circumstances after the date hereof, except as required by law.

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: *April 11, 2013*

By: /s/ Glenn F. Baity

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