ACADIA PHARMACEUTICALS INC
Form 8-K
December 09, 2011

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 9, 2011

Commission File Number: 333171722

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.

ACADIA Pharmaceuticals Inc. ("Registrant") will present a poster entitled, "Optimization of Phase III Study Design for Pimavanserin in the Treatment of Parkinson's Disease Psychosis (PDP)" at the XIX World Congress of Parkinson's Disease and Related Disorders, which will be held from December 11-14, 2011 in Shanghai, China. The poster includes information on study enhancements that have been designed to mitigate placebo response and reduce variability in the ongoing Phase III trial with pimavanserin for Parkinson's disease psychosis. These study-design enhancements include, but are not limited to, strengthened criteria to assure patients have moderate to severe psychotic symptoms at study entry, conduct of the study only in North America where a central rating system employing a small number of independent, blinded raters is used to assess the trial's primary endpoint, and use of a refined 9-item SAPS H+D scale for the primary endpoint in order to improve specificity and reduce data variability.

Analysis of data from an earlier, completed Phase III trial with pimavanserin for PDP (the "-012 study"), for which Registrant announced the top-line results in 2009, support the study-design enhancements made for the ongoing Phase III study. In the earlier -012 study, the 40 mg pimavanserin arm, US data only, showed a trend toward significance ($p = 0.0993$) versus placebo. Retrospective analysis of this US data from the 012 study using the modified 9-item SAPS scale showed enhanced separation of the 40 mg pimavanserin arm from placebo ($p = 0.0498$). After considering additional factors, including disease severity at study entry, retrospective analysis of the -012 study showed a further moderation in placebo response and more marked separation of treatment effect in the 40 mg pimavanserin arm.

Forward-Looking Statements

Certain statements in this report that are not historical facts are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements relating to the benefits to be derived from changes to clinical trial designs for the Registrant's ongoing Phase III trial for Parkinson's disease psychosis. 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 stated in any such statements due to various factors, including the risks and uncertainties inherent in drug development and clinical trials, and the fact that past results of clinical trials may not be indicative of future trial results, as well as other factors, some of which are discussed in ACADIA's annual report on Form 10-K for the year ended December 31, 2010 as well as other 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.

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 9, 2011*

By: /s/ Glenn F. Baity

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