ACADIA PHARMACEUTICALS INC
Form 8-K
June 18, 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): June 18, 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.

ACADIA Pharmaceuticals Inc. presented data from its Phase III program with pimavanserin for Parkinson's disease psychosis ("PDP"), including data from its pivotal Phase III study (the "-020 Study") and the related, open-label safety extension study (the "-015 Study"), at a poster session at the 17th International Congress of Parkinson's Disease and Movement Disorders, which is taking place in Sydney, Australia from June 17 - 20, 2013. As of March 2013, a total of 458 PDP patients from 14 countries with a mean age at study-entry of 71 years had rolled over into the -015 Study from the -020 Study and two earlier six-week placebo-controlled trials, the -012 and -014 studies. During the open-label study, patients receive 40 mg of pimavanserin daily and evaluations occur at week 2 and at months 1, 3, 6, 9 and 12, as well as every 6 months thereafter. About half of the patients in the open-label -015 Study have stayed on pimavanserin for more than a year. The data suggest that long-term administration of 40 mg of pimavanserin is generally safe and well tolerated in patients with PDP. The majority of adverse events observed in the -015 Study were mild to moderate and no change in the pattern or severity of events was observed with time on study. The adverse event profile observed for the open-label study has been similar to that seen in the 6-week blinded, placebo-controlled studies. In addition, the rate of discontinuation due to adverse events in the -015 Study appears to be lower than that recently reported in a third-party study of patients over 40 years old who used one of four commonly prescribed atypical antipsychotic drugs, olanzapine, risperidone, quetiapine and aripiprazole. In the 6-week PDP studies, the 40 mg pimavanserin arms produced small but consistent mean increase in QTcB (~7-9 msec) with no associated clinical effects. In the -015 Study, no exacerbation of this effect was observed.

Although there are no formal efficacy endpoints in the open-label -015 Study, antipsychotic effect was measured at one month using the SAPS-PD scale and at all study visits using the Clinical Global Impression Improvement ("CGI-I") scale and the Clinical Global Impression Severity ("CGI-S") scale. The CGI data are intended to provide the investigator with information to determine whether patients continue to derive benefit from pimavanserin during the open-label study. Patients who entered the -015 Study from the 40 mg treatment arms of the previous six-week studies maintained about the same mean improvement in SAPS-PD scores one month later. Patients who entered the -015 Study from the placebo arms of the previous six-week studies displayed a marked improvement in mean SAPS-PD scores after one month in the -015 Study. In addition, the long-term CGI data indicate durability of treatment effect for patients remaining in the open-label study.

In a separate poster, ACADIA presented the effects on sleep and daytime wakefulness that were assessed in the previously reported -020 Study. Although the -020 Study did not require sleep impairment at entry, pimavanserin demonstrated a significant improvement in nighttime sleep at weeks 4 and 6 compared to placebo. Patients who entered the -020 Study with severe nighttime disturbances (i.e., those having a baseline score of at least 7 on the Scales for Outcome in Parkinson's Disease - Nighttime Sleep, or SCOPA-NS) benefitted the most from pimavanserin therapy and showed highly significant nighttime sleep improvements at weeks 2, 4 and 6 compared to placebo. The positive effect of pimavanserin on nighttime sleep and daytime wakefulness did not correlate with antipsychotic measures, thus indicating that the sleep and wakefulness improvements of pimavanserin seen in the -020 Study may represent treatment benefits independent from the antipsychotic efficacy.

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 ACADIA's drug discovery and development programs, the benefits to be derived from ACADIA's product candidates, in each case including pimavanserin, the potential sleep and wakefulness improvements or long-term antipsychotic benefits from treatment with pimavanserin, and the potential benefits of pimavanserin in comparison to commonly prescribed atypical antipsychotics. 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, 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, 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 press release 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: *June 18, 2013*

By: /s/ Glenn F. Baity

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