ACADIA PHARMACEUTICALS INC
Form 8-K
November 27, 2012

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): November 27, 2012

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.

On November 27, 2012, ACADIA Pharmaceuticals Inc. announced successful top-line results from its pivotal Phase III trial evaluating the efficacy, tolerability and safety of pimavanserin in patients with Parkinson's disease psychosis, or PDP. Pimavanserin met the primary endpoint in the Phase III trial by demonstrating highly significant antipsychotic efficacy as measured using the 9-item SAPS-PD scale (p=0.001). Pimavanserin also met the key secondary endpoint for motoric tolerability as measured using Parts II and III of the Unified Parkinson's Disease Rating Scale, or UPDRS. These results were further supported by a highly significant improvement in the secondary efficacy measure, the Clinical Global Impression Improvement, or CGI-I, scale (p=0.001). In addition, clinical benefits were observed in all exploratory efficacy measures with significant improvements in nighttime sleep, daytime wakefulness, and caregiver burden. Consistent with previous studies, pimavanserin was safe and well tolerated in the Phase III trial. A copy of ACADIA's press release related to the top-line results is attached as Exhibit 99.1.

Primary Endpoint

The primary endpoint of the trial was antipsychotic efficacy as measured using the SAPS-PD, a 9-item scale adapted from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms, by comparing the mean change from baseline to day 43 for pimavanserin versus placebo. SAPS-PD assessments were performed by blinded, independent centralized raters. Treatment with pimavanserin resulted in a 5.79 point improvement in psychosis at day 43 compared to a 2.73 point improvement for placebo, representing a highly significant and clinically meaningful treatment difference of 3.06 points on SAPS-PD (p=0.001).

	Baseline Mean		Mean Change at Day 43		
	PBO (n=90)	PIM (n=95)	PBO	PIM	P-value
SAPS-PD	14.73	15.88	-2.73	-5.79	0.001

Note: mixed model repeated measures (MMRM) method was applied in the primary analysis of the intent-to-treat (ITT) population. The significance test was based on least-square mean change from baseline for each arm using a 2-sided beta = 0.05.

Key Secondary Endpoint

The key secondary endpoint of the trial evaluated motoric tolerability and functional outcome using Parts II and III of the UPDRS. The objective of this secondary endpoint was to demonstrate that pimavanserin could achieve its antipsychotic effects without worsening motor function as compared to placebo in PDP patients. A pre-specified, non-inferiority analysis was used to compare the mean change from baseline to day 43 for pimavanserin versus placebo using a two-sided 95 percent confidence interval (CI) for the treatment difference. Motoric improvements were seen in both the pimavanserin and placebo arms. The CI associated with the treatment difference did not exceed a pre-specified margin of 5 points for clinically relevant change, confirming that pimavanserin met this key secondary endpoint and did not worsen motor function in PDP patients.

Secondary and Exploratory Efficacy Measures

The secondary efficacy measure in the trial was an assessment of clinical global improvement by the investigator using the CGI-I scale. Pimavanserin demonstrated a highly significant improvement on this measure (p=0.001), further supporting its antipsychotic efficacy.

Other exploratory efficacy measures included sleep and caregiver burden. Sleep was assessed using the SCOPA-sleep scale, which was designed to enable the investigator to evaluate nighttime sleep and daytime wakefulness in Parkinson's patients. Pimavanserin demonstrated significant improvements on both nighttime sleep (p=0.045) and daytime wakefulness (p=0.012) on SCOPA.

Caregiver burden was assessed using the Caregiver Burden Scale. This scale was completed by the caregiver to provide a quantitative assessment of burden associated with the patient's functional/behavioral impairments, the circumstances of at-home care, as well as the caregiver's health, social life and interpersonal relations. Pimavanserin demonstrated a highly significant improvement on the Caregiver Burden Scale (p=0.002).

Safety and Tolerability

Consistent with previous studies, pimavanserin was safe and well tolerated in this trial. Based on a preliminary analysis of safety data, the most common adverse events were urinary tract infection (11.7% PBO vs. 13.5% PIM) and falls (8.5% PBO vs. 10.6% PIM). The other adverse events that occurred with 5% or greater frequency in either study arm were peripheral edema, hallucination, confusional state, nausea and headache. Adverse events were generally characterized as mild to moderate in nature. The only serious adverse events that occurred in more than one patient were urinary tract infection (1-PBO vs. 3-PIM) and psychotic disorder (0-PBO vs. 2-PIM). There were three deaths that occurred during the study (1-PBO vs. 2-PIM), but they were all considered unrelated to study drug. Ninety percent of the patients who completed the clinical phase of this trial elected to roll over into the ongoing open-label safety extension study. Patients were only eligible to participate in the extension study if the treating investigator also deemed them to be likely to benefit from continued treatment with pimavanserin.

Trial Design

The pivotal Phase III trial, referred to as the -020 Study, was a multi-center, double-blind, placebo-controlled study designed to evaluate the efficacy, tolerability and safety of pimavanserin as a treatment for patients with PDP. A total of 199 patients were enrolled in the study and randomized on a one-to-one basis to receive either 40 mg of pimavanserin or placebo once-daily for six weeks, following a two-week screening period including brief psycho-social therapy. Patients also received stable doses of their existing anti-Parkinson's therapy throughout the study.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished herewith:

99.1 Press release dated November 27, 2012.

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: November 27, 2012

By: /s/ Thomas H. Aasen
Name: Thomas H. Aasen
Title: Executive Vice President, Chief Financial Officer and Chief Business Officer