ACADIA PHARMACEUTICALS INC
Form 8-K
October 31, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 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): October 31, 2018

ACADIA Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-50768**	**061376651**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3611 Valley Centre Drive, Suite 300

San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (858) 558-2871

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On October 31, 2018, ACADIA Pharmaceuticals Inc. announced positive top-line results from CLARITY, a randomized, double-blind, placebo-controlled multi-center, sequential parallel comparison design study in major depressive disorder (MDD). A copy of ACADIA s press release announcing the top-line results is attached as Exhibit 99.1.

Trial Design and Top-line Results

CLARITY was a Phase 2, 10-week, randomized, double-blind, placebo-controlled, multi-center, 2-stage sequential parallel comparison design (SPCD) study that evaluated the safety, tolerability and efficacy of pimavanserin (34 mg once daily) as an adjunctive treatment in patients with MDD who had inadequate response to a stable dose of standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). The study was conducted in collaboration with the MGH Clinical Trials Network & Institute and randomized 207 patients across 28 clinical research centers in the United States.

Consistent with the SPCD design, CLARITY was conducted in two five-week sequential stages. Eligible subjects continued receiving their SSRI/SNRI antidepressant at a stable dose for the duration of the study. Patients were randomly assigned (1:3) to pimavanserin 34 mg/day or placebo in Stage 1. Placebo non-responders in Stage 1 (defined as HAMD-17 total score >14 and a percent-reduction from baseline in HAMD-17 total score of <50% at week 5) were re-randomized (1:1) to receive pimavanserin 34 mg/day or placebo. The primary endpoint of the study was the change in HAMD-17 total score for Stage 1 and Stage 2. Treatment differences from Stage 1 and Stage 2 were combined as weighted averages.

In the trial, pimavanserin met the overall primary endpoint of the weighted average results of Stage 1 and Stage 2 by significantly reducing the HAMD-17 total score compared to placebo (p=0.039). In addition, in Stage 1 (n=207) patients on pimavanserin demonstrated a highly significant improvement in HAMD-17 (p=0.0003). Importantly, this group of patients saw a benefit over placebo in the first week of treatment (p=0.0365). Stage 2 (n=58) results did not demonstrate significant separation in this small set of placebo non-responders.

On the key secondary endpoint, pimavanserin demonstrated statistically significant reductions compared to placebo in the Sheehan Disability Scale (SDS) score (p=0.004). Positive results were also observed for seven other secondary endpoints listed below with nominal p values: Clinical Global Impression-Severity (p=0.0084), Clinical Global Impression-Improvement (p=0.0289), Short Form-12 Mental Component Summary (p<0.0001), Karolinska Sleepiness Scale (p=0.0205), Massachusetts General Hospital Sexual Functioning Index (p=0.0003), Barratt Impulsiveness Scale (p=0.0075), as well as response rates (p=0.0065), defined as a 50% or greater reduction on the HAMD-17 total scale.

A post-hoc comparison between pimavanserin (n=51) and placebo (n=123) for patients consistently receiving either placebo or pimavanserin for the entire 10-week period also yielded meaningful separation with positive p-values at all weeks starting from week 2 to week 10 in favor of pimavanserin for both the primary endpoint, HAMD-17 (week 10, p=0.0076), and the key secondary endpoint, SDS (week 10, p=0.0094).

Safety and Tolerability

In CLARITY, pimavanserin was generally well-tolerated. Discontinuations due to adverse events were 1.2% for pimavanserin and 3.2% for placebo. One subject in each of the pimavanserin and placebo groups reported serious adverse events (SAEs). These SAEs were deemed not to be related to the study drug by the investigators and both subjects completed the study. No deaths were reported in the study.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished herewith:

99.1 Press release dated October 31, 2018

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.

Date: October 31, 2018

ACADIA Pharmaceuticals Inc.

By: /s/ Austin D. Kim
Name: Austin D. Kim
Title: Executive Vice President, General Counsel & Secretary