ARENA PHARMACEUTICALS INC
Form 8-K
September 24, 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): September 24, 2018

Arena Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	000-31161	23-2908305
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
6154 Nancy Ridge Drive, San Diego, CA		92121
(Address of Principal Executive Offices)		(Zip Code)

Registrant’s Telephone Number, Including Area Code: (858) 453-7200

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 Instructions 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))
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.

In this report, “Arena Pharmaceuticals,” “Arena,” “Company,” “we,” “us” and “our” refer to Arena Pharmaceuticals, Inc., and/ one or more of our wholly owned subsidiaries, unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc.

Item 8.01 Other Events.

Topline Phase 2a Results for Olorinab in Patients with Abdominal Pain Associated with Crohn’s Disease

On September 24, 2018, we announced positive topline results from our Phase 2a trial of olorinab, an investigational, peripherally restricted, highly selective, full agonist of the cannabinoid receptor 2 (CB_2) in development for the treatment of gastrointestinal pain.

Phase 2a Trial Design

This was a randomized, open-label, 8-week study investigating two doses of olorinab (25 mg and 100 mg) administered TID (three times daily). All patients were diagnosed with quiescent to mild active Crohn’s disease associated with chronic abdominal pain defined as a baseline Average Abdominal Pain Score (AAPS) ≥4. Fourteen patients were enrolled with a mean baseline AAPS of 5.6.

Topline Analyses

Reductions in pain were seen within the first week of treatment with olorinab and statistically significant improvement from baseline in AAPS was observed at weeks 4 and 8. In the 11 patients evaluable at 8 weeks of treatment (baseline AAPS = 6.0), there was an improvement in AAPS of -4.6 ($p<0.001$) from baseline at peak effect (1.5 hours post morning dose). At peak effect, 11 out of 13 patients (85%) with evaluable data at week 4, and 11 out of 11 patients (100%) with evaluable data at week 8, exhibited a clinically relevant improvement (≥30% change from baseline) in AAPS. Results in all patients randomized (intent-to-treat) demonstrated 11 out of 14 patients (79%) with clinically relevant improvement at both weeks 4 and 8. The improvement in pain was consistent at both the 25 mg and 100 mg olorinab dose levels and a statistically significant improvement in AAPS was also observed at trough levels (before the morning dose).

Olorinab appeared safe and generally well tolerated in this study with no clinically significant changes in heart rate or blood pressure, no psychotropic effects, and no discontinuations due to adverse events.

About the Trial

The Phase 2a study was a randomized, open-label, 8-week trial to assess the safety, tolerability, efficacy and pharmacokinetics of two orally administered doses (25 mg and 100 mg TID) of olorinab (APD371) in patients with Crohn's disease experiencing abdominal pain. The trial enrolled 14 patients with an Average Abdominal Pain Score (AAPS) ≥4. The safety assessment included adverse events, physical examination, clinical laboratory tests (including hematology, serum chemistry and urinalysis), ECGs and vital signs monitored throughout the study. The efficacy assessment included change in AAPS from baseline, and proportion of responders (defined as a >30% improvement in AAPS) determined at three time points (before the morning dose of olorinab, 1.5 hours after the morning dose, and before the evening dose) throughout the study. In addition, the impact of 8 weeks treatment with olorinab on inflammatory markers of Crohn’s disease and Patient Reported Outcomes/Health Questionnaires was assessed.

About Olorinab

Olorinab (APD371) is an oral, peripherally restricted, highly selective, full agonist of the cannabinoid receptor 2 (CB_2) in development for the treatment of gastrointestinal-based visceral pain associated with gastrointestinal diseases, including Crohn's disease. Arena discovered and developed this drug candidate internally. Olorinab showed sustained efficacy in several preclinical models of chronic pain (including inflammatory bowel disease) and appeared safe and well tolerated in Phase 1 single and multiple dose studies. In a Phase 1 study of healthy volunteers, olorinab produced no psychotropic effects commonly seen with cannabinoids, supporting its potential application as an analgesic without risk of abuse or dependence.

Olorinab is an investigational compound that is not approved for any use in any country.

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be identified by introductory words such as "in development for," "potential," or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements regarding olorinab's potential applications and risks. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include the following: the topline data is based on preliminary analysis of key data, and such data or analysis may change following a more comprehensive review of the data, and such topline data may not accurately reflect the complete results of a particular study or trial; the reported-on Phase 2a trial was not a placebo controlled study; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; nonclinical and clinical data are voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than us or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; the timing and outcome of

research, development and regulatory review is uncertain; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling patients in our ongoing and intended clinical trials is competitive and challenging; unexpected or unfavorable new data; risks related to developing and commercializing drugs; risks related to relying on partners and other third parties; our and third parties' intellectual property rights; and satisfactory resolution of litigation or other disagreements with others. Additional factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements are disclosed in our filings with the Securities and Exchange Commission (SEC), including but not limited to our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. These forward-looking statements represent our judgment as of the time of this release. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable 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 thereunto duly authorized.

Date: September 24, 2018 Arena Pharmaceuticals, Inc.

By: /s/ Amit D. Munshi
Amit D. Munshi
President and Chief Executive Officer