ARENA PHARMACEUTICALS INC
Form 8-K
October 02, 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 2, 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.

Long-Term Data from the Ongoing Open-Label Extension of the Phase 2 Trial Evaluating Ralinepag for Treatment of Pulmonary Arterial Hypertension

On October 2, 2018, we announced positive data from a planned interim analysis of the ongoing open-label extension of the Phase 2 trial of our investigational drug candidate ralinepag, a next-generation, oral, selective and potent prostacyclin receptor agonist in development for the treatment of pulmonary arterial hypertension (PAH).

Open-Label Extension of Phase 2 Trial Design

This is an open-label extension study evaluating the long-term safety, tolerability and efficacy of ralinepag in 45 patients (85% of study completers) who completed the Phase 2 randomized study. In the extension study, patients originally randomized to ralinepag continued on active therapy (N=30); patients randomized to placebo switched to ralinepag (N=15). Key efficacy measurements include pulmonary vascular resistance (PVR) and 6-minute walk distance (6MWD).

Key Efficacy and Safety Measurements

Patients who continued on ralinepag in the open-label extension had a median treatment duration of 1.8 years (range 1.2-3.4 years) at the time of right heart catheterization (RHC). In these patients, sustained improvements from baseline in the original study were observed for PVR (219 dyn*s*cm -5 median reduction, p = 0.002) and 6MWD (49.8 meters mean improvement; p = 0.003). Patients switching from placebo to active drug had a median ralinepag treatment duration of 1.4 years (range 0.9-2.3 years) at the time of RHC. In these patients, a similar magnitude of improvement was observed for PVR (214 dyn*s*cm -5 median reduction, p = 0.206) and 6MWD (69.8 meters mean improvement; p = 0.010). In both groups, these long-term changes in PVR and 6MWD were observed in a population where the majority of patients were already receiving dual combination PAH background therapy.

Adverse events (AEs) observed in this extension study were consistent with the known profile of prostacyclin therapies for the management of PAH, with headache and nausea being the most commonly reported. Among patients who continued ralinepag in the open-label extension, the incidence rate of AEs was lower relative to the randomized Phase 2 study, suggesting that AEs related to tolerability are reduced after initial drug titration.

About Ralinepag

Ralinepag (APD811) is a next-generation, oral, selective potent, once-daily IP receptor agonist intended for the treatment of pulmonary arterial hypertension (PAH). We discovered and developed this drug candidate internally. Ralinepag's potency on vasodilation, inhibition of proliferation of vascular smooth muscle cells, and inhibition of platelet aggregation, combined with an extended half-life, support its application as a potentially best-in-class agent for the treatment of PAH.

Ralinepag 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," "evaluating," "suggesting," "intended for," "potentially," 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 the intention and plan to progress ralinepag's development; the potential reduction in adverse events related to tolerability after initial drug titration; and ralinepag's potential, including to be best-in-class for the treatment of PAH. 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 announced data are based on an interim analysis of certain key measurements, and such interim data or analysis may change following a more comprehensive review of the data, and such interim data or analysis may not accurately reflect the final results of the study; the reported-on 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: October 2, 2018 Arena Pharmaceuticals, Inc.

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