ARENA PHARMACEUTICALS INC
Form 8-K
July 10, 2017
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): July 10, 2017

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 7.01 Regulation FD Disclosure.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical data results discussed in Item 8.01 below as well as updates to the Company’s program pipeline. The Company intends to present the slides during a conference call and live webcast with the investment community on July 10, 2017, at 4:30 p.m. EDT.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Topline Phase 2 Results for Ralinepag

On July 10, 2017, the Company announced positive Phase 2 results for ralinepag, an investigational, long-acting, orally administered prostacyclin receptor agonist under development for the treatment of pulmonary arterial hypertension (PAH). In this 61-patient study, the primary efficacy analysis demonstrated a statistically significant absolute change from baseline in pulmonary vascular resistance (PVR) compared to placebo. Ralinepag also demonstrated numerical improvement in 6-minute walk distance (6MWD).

Ralinepag improved median PVR by 163.9 dyn.s.cm-5 from baseline compared to a 0.7 dyn.s.cm-5 worsening from baseline in the placebo arm (P=0.02). Patients treated with ralinepag had a 29.8% improvement in PVR compared to the placebo arm (P=0.03) and a 20.1% improvement in PVR compared to baseline. Additionally, adverse events observed in the study were consistent with other prostacyclin treatments for the management of PAH, with headache, nausea, diarrhea, jaw pain and flushing being the most commonly reported adverse events. The Company plans to present full study results at future medical congresses.

The Phase 2 study was a randomized, double-blind, placebo-controlled, dose-ranging study in 61 adult patients with PAH, WHO/NYHA functional class II-IV. Study medication was titrated over 9 weeks, followed by a 13-week treatment period. The primary efficacy analysis was absolute change from baseline in PVR at week 22. Additional endpoints included change from baseline in 6-minute walk test, proportion of subjects who exhibit clinical worsening and safety and tolerability. Patients who completed week 22 could transition to an open-label ralinepag extension study.

Ralinepag (APD811) is an oral, next-generation, selective IP receptor agonist targeting the prostacyclin pathway and intended for the treatment of PAH. The Company discovered and developed this drug candidate internally. Ralinepag is an investigational compound that is not approved for any use in any country.

Item 9.01 Financial Statements and Exhibits. (d) Exhibits.

Exhibit No.	Description
99.1	Slide presentation dated July 10, 2017, titled “Ralinepag Phase 2 Clinical Results.”

Forward-Looking Statements

Statements in this report on Form 8-K that are not statements of historical fact are forward-looking statements, which involve a number of risks and uncertainties. Such statements include statements about the Company’s plans to present full study results; transitioning patients to an open-label extension study; ralinepag’s potential; and other statements that are not historical facts, including statements that may include the words “plans” and “could”. 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: top-line data may not accurately reflect the complete results of a particular study or trial; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical and nonclinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements; 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; risks related to developing, seeking regulatory approval and commercializing drugs; unexpected or

unfavorable new data; Arena's and third parties' intellectual property rights; clinical trials and other studies may not proceed at the time or in the manner expected or at all; data and information related to our programs may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, partnering or approval; competition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and their availability and use; reimbursement and pricing decisions; risks related to relying on partners and other third parties; and satisfactory resolution of litigation or other disagreements; and those factors disclosed in Arena’s filings with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended March 31, 2017. These forward-looking statements represent our judgment as of the time of this report on Form 8-K. 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: July 10, 2017 Arena Pharmaceuticals, Inc.

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

Exhibit Index

Exhibit Number	Description
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