ARENA PHARMACEUTICALS INC
Form 8-K
July 11, 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 11, 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,		**92121**

San Diego, CA	
(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., 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 2.02 Results of Operations and Financial Condition.

On July 11, 2017, we filed a preliminary prospectus supplement with the Securities and Exchange Commission, or the SEC, in which we disclosed that we had cash and cash equivalents as of June 30, 2017 of $130.8 million, which includes approximately $0.2 million of cash held by Beacon Discovery, Inc., a variable interest entity.

Item 8.01 Other Events.

We are filing the following information with the SEC for the purpose of updating certain aspects of the description of our business disclosed in our SEC reports.

Overview

We are a biopharmaceutical company focused on developing novel, small-molecule drugs with optimized receptor pharmacology designed to deliver broad clinical utility across multiple therapeutic areas. Our proprietary pipeline includes potentially first- or best-in-class programs for which we own global commercial rights.

Our three most advanced clinical programs are:

Ralinepag (formerly APD811) - an oral, next generation, selective IP receptor agonist targeting the prostacyclin pathway, for which we have reported positive topline results from our completed Phase 2 trial for pulmonary arterial hypertension, or PAH. Phase 3 trial preparations are ongoing.

Etrasimod (formerly APD334) - an oral, next generation, selective sphingosine 1-phosphate, or S1P, receptor modulator targeting the S1P receptor subtypes 1, 4 and 5, which we are evaluating in multiple ongoing Phase 2 clinical trials for:

- Ulcerative Colitis, or UC
- Dermatological Extra-Intestinal Manifestations, or Derm EIMs, in Inflammatory Bowel Disease, or IBD
- Pyoderma Gangrenosum, or PG, with and without co-morbidities including IBD

We also intend to initiate an additional trial in Primary Biliary Cholangitis, or PBC, in 2017.

APD371 - a highly selective, peripherally restricted, orally available, full agonist of the cannabinoid-2 receptor, which we are evaluating in an ongoing Phase 2 clinical trial for pain associated with Crohn s disease We intend to continue to explore additional indications for all of our clinical-stage programs.

Additionally, we have collaborations with the following pharmaceutical companies:

Eisai Inc. and Eisai Co., Ltd. in their efforts with respect to BELVIQ®

Axovant Sciences Ltd. in its efforts with respect to nelotanserin, an orally available inverse agonist of the serotonin 2A receptor, which is in (i) a Phase 2 clinical trial in Lewy body dementia patients who experience frequent visual hallucinations, and (ii) a separate Phase 2 clinical trial to evaluate nelotanserin as a potential treatment for rapid-eye-movement, or REM, behavior disorder in patients with dementia with Lewy bodies

Boehringer Ingelheim International GmbH targeting a G protein-coupled receptor that belongs to the group of orphan central nervous system receptors, which is in preclinical development

Recent Developments

Ralinepag

On July 10, 2017, we announced positive Phase 2 results for ralinepag. In this study, the primary efficacy analysis demonstrated a statistically significant absolute change from baseline in pulmonary vascular resistance, or PVR, compared to placebo. Ralinepag also demonstrated numerical improvement in 6-minute walk distance, or 6MWD.

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 nine 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 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. The study was not powered to show a difference in 6MWD from placebo and, while between group comparison directionally favored ralinepag, this was a not a statistically-significant finding. Patients receiving ralinepag did demonstrate a 36m increase from baseline, a statistically significant within group increase.

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. Serious adverse events occurred in four (10%) of the patients taking ralinepag and in six (28.6%) of the patients taking placebo. There were no deaths among the patients taking ralinepag and there were two deaths in the placebo group.

We plan to present full study results at future medical congresses.

Etrasimod

We had previously reported that the etrasimod Phase 2 study in ulcerative colitis would enroll up to 160 patients. We currently expect the final enrollment to be in the range of 120-160 patients.

APD371

We recently announced the design of the ongoing Phase 2a investigation into the treatment of pain associated with Crohn s disease. The study is a randomized, open-label, study to evaluate tolerability, pharmacokinetics, and efficacy in up to 20 subjects with Crohn s disease pain.

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.

Arena Pharmaceuticals, Inc.

Date: July 11, 2017

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