ARENA PHARMACEUTICALS INC
Form 8-K
January 06, 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): January 6, 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))

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 2.02 Results of Operations and Financial Condition.

Commencing on January 8, 2017, we expect to disclose the following information in discussions to be held in connection with the Annual J.P. Morgan Healthcare Conference: As of December 31, 2016, Arena Pharmaceuticals, Inc. (the “Company”) had approximately $90 million of cash and cash equivalents. See additional information in the presentation furnished as an Exhibit to Item 7.01.

Item 7.01 Regulation FD Disclosure.

Included as Exhibit 99.1 to this Form 8-K is a presentation titled “Corporate Presentation – JP Morgan Healthcare Conference”, dated January 2017, which is incorporated herein by reference. We intend to utilize this presentation in various meetings with securities analysts, investors and others in connection with the Annual J.P. Morgan Healthcare Conference, commencing on January 8, 2017.

The information contained 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.

We are providing the following information to summarize and update certain aspects of our publicly disclosed description of our clinical programs.

Etrasimod

Etrasimod, an orally available modulator of the S1P receptor, is our internally discovered investigational drug candidate intended for the potential treatment of a number of autoimmune diseases. S1P receptor modulators have been demonstrated to be involved in several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood. By isolating lymphocytes in lymph nodes, fewer immune cells are available in the circulating blood to effect tissue damage. Drugs in this class have been associated with certain side effects, including cardiovascular effects, respiratory effects, infection, macular edema and elevations in liver enzymes. We have optimized etrasimod as a potent and selective small molecule S1P receptor modulator that reduces the severity of disease in preclinical autoimmune-disease models.

We are currently developing etrasimod for ulcerative colitis. In July 2015, we initiated patient dosing in a 12-week, randomized, double-blind and placebo-controlled Phase 2 clinical trial of etrasimod for ulcerative colitis. We are working diligently to obtain data from this trial by the end of 2017. To achieve our goal of obtaining data from this trial by the end of 2017 and lower costs, we are assessing potential changes to the trial protocol that we believe would improve data readout and enhance overall efficiency of the trial, while maintaining study conduct, data integrity, patient safety and the overall study objectives.

In addition, to further enhance the overall profile of our etrasimod program, we intend to explore development in additional indications, including

- Dermatological Extra-Intestinal Manifestations (EIM) in Inflammatory Bowel Disease (IBD)
- Pyoderma Gangrenosum (PG)

- Primary Biliary Cirrhosis (PBC)

We are designing exploratory Phase II clinical trials for each of these additional indications. We intend to initiate these Phase II trials during 2017.

Ralinepag

Ralinepag, an oral, selective IP receptor agonist targeting the prostacyclin pathway, is our internally discovered investigational drug candidate intended for the treatment of pulmonary arterial hypertension, or PAH. In September 2014, ralinepag was granted orphan drug status for the treatment of PAH by the FDA.

In January 2015, we initiated patient dosing in a 22-week, randomized, double-blind and placebo-controlled Phase 2 clinical trial of ralinepag. We completed enrollment in the trial in December 2016 and expect to obtain data from this trial by the end of the third quarter of 2017.

APD371

APD371, an orally available, peripherally restricted, highly selective, full agonist of the cannabinoid-2 (CB2) receptor, is an internally discovered investigational drug candidate we are exploring for the treatment of pain.

In October 2015, we initiated a Phase 1 multiple-ascending dose trial of APD371. In the first half of 2016, we completed this trial with favorable results. In the first quarter of 2017, we intend to commence a Phase 2 clinical trial of APD371 for pain associated with Crohn's disease and expect to obtain data from this trial by the end of 2017.

Temanogrel

Temanogrel, an orally available inverse agonist of the serotonin 2A receptor, is an internally discovered investigational drug candidate intended for the treatment of thrombotic diseases. We believe temanogrel has the potential to inhibit serotonin-mediated platelet aggregation and vasoconstriction. We believe temanogrel's dual mechanism may be therapeutically useful for the treatment or prevention of thrombotic diseases.

We previously completed a Phase 1a clinical evaluation of temanogrel, and provided Ildong Pharmaceuticals Co., Ltd., the development and commercialization rights to temanogrel in South Korea (while we retained all other rights worldwide). Ildong is not currently advancing temanogrel in clinical trials for South Korea. We are continuing to evaluate options for this program.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation – JP Morgan Healthcare Conference

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 forward-looking statements include, without limitation, statements about the timing of obtaining data from clinical trials, changes in clinical protocol, and planned or intended clinical trials and indications. Words such as "believe," "plan," "expect," "intend," "will," "would," "may," "goal," "potential" and sim expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. 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, but are not limited to, the risk that we may not be able to recruit patients for certain trials as anticipated, and the risk that we may not successfully implement

anticipated changes in clinical protocol, as well as risks related to: research and development; regulatory approval; commercialization; competition; intellectual property; and our financial and other resources. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in our filings with the Securities and Exchange Commission. 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: January 6, 2017 Arena Pharmaceuticals, Inc.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Corporate Presentation – JP Morgan Healthcare Conference