ARENA PHARMACEUTICALS INC
Form 8-K
January 09, 2015

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 7, 2015

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-31161**	**23-2908305**
(State or other jurisdiction	**(Commission**	**(I.R.S. Employer**

of incorporation) **File Number)** **Identification No.)**

6154 Nancy Ridge Drive, San Diego, California 92121

(Address of principal executive offices) (Zip Code)

858.453.7200

(Registrant s telephone number, including area code)

N/A

(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:

¨ 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., 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. BELVIQ® is a registered trademark of our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

On January 7, 2015, we announced top-line results from a Phase 1b multiple ascending dose clinical trial for APD334, an oral drug candidate that targets the sphingosine 1-phosphate subtype 1, or $S1P_1$, receptor for the potential treatment of autoimmune diseases.

In the Phase 1b clinical trial, APD334 demonstrated a dose-dependent effect on lymphocyte count lowering in blood, with mean decreases from baseline of up to 69%. Lymphocyte counts, on average, recovered to baseline within one week of conclusion of dosing. There were no clinically significant safety findings with respect to heart rate or rhythm or pulmonary function, and no clinically significant elevations in liver enzyme tests. The most common treatment-emergent adverse events were mild or moderate contact dermatitis, headache, constipation and diarrhea, with none being clearly drug related. There were no discontinuations for adverse events, and no serious adverse events were observed.

The randomized, double-blind, placebo-controlled Phase 1b clinical trial evaluated the safety, tolerability, pharmacodynamics and pharmacokinetics of multiple-ascending doses of APD334. In five different dosing cohorts, a total of 50 healthy volunteers received APD334 and 10 received placebo for 21 days.

We plan to advance APD334 into Phase 2 clinical trials in 2015 for ulcerative colitis and Crohn s disease.

About Autoimmune Diseases

Autoimmune diseases, such as multiple sclerosis, psoriasis, ulcerative colitis, Crohn s disease and rheumatoid arthritis, are characterized by an inappropriate immune response against substances and tissues that are normally present in the body. In an autoimmune reaction, a person s antibodies and immune cells target healthy tissue, triggering an inflammatory response. Reducing the immune and/or inflammatory response is an important goal in the treatment of autoimmune diseases.

About APD334

APD334 is a potent and selective, orally available investigational drug candidate that targets the $S1P_1$ receptor. Discovered by us, APD334 has therapeutic potential in autoimmune diseases. $S1P_1$ receptors have been demonstrated to be involved in the modulation of 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.

Forward-Looking Statements

Certain statements in this Form 8-K are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the therapeutic indication, use, safety, efficacy, mechanism of action, and potential of APD334, including as a potential treatment for one or more autoimmune diseases; the significance of the trial results for APD334, including with respect to lymphocyte lowering and safety; the significance of reducing the immune and/or inflammatory response; and advancing development of APD334, including future trials and investigated indications. 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 following: top-line results are not comprehensive and are based on a preliminary analysis of then available data, and findings and conclusions related to the trial are subject to change following a more comprehensive review of the data; APD334 may not be developed, approved for marketing or commercialized for any disease or condition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ, including the impact of competition; our revenues will be based in part on estimates, judgment and accounting policies, and

incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to our guidance or previously reported results; the timing and outcome of regulatory review is uncertain, and BELVIQ may not be approved for marketing when expected or ever in combination with another drug, for another indication or using a different formulation or in any other territory for any indication; regulatory decisions in one territory may impact other regulatory decisions and our business prospects; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative arrangements; the timing and receipt of payments and fees, if any, from collaborators; the entry into or modification or termination of collaborative arrangements; unexpected or unfavorable new data; nonclinical and clinical data is 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; data and other information related to any of our research and development may not meet regulatory requirements or otherwise be sufficient for (or we or a collaborator may not pursue) further research and development, regulatory review or approval or continued marketing; our and third parties intellectual property rights; the timing, success and cost of our research and development; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner expected or at all; having adequate funds; 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. These forward-looking statements represent our judgment as of the time of the filing of this Form 8-K. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

SIGNATURE

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 hereunto duly authorized.

Date: January 9, 2015

Arena Pharmaceuticals, Inc.

By: /s/ Steven W. Spector
Steven W. Spector
Executive Vice President, General Counsel and Secretary