

ARENA PHARMACEUTICALS INC
Form 8-K
April 05, 2013

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): April 5, 2013

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-31161
(Commission
File Number)

23-2908305
(I.R.S. Employer
Identification No.)

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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., unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

On April 5, 2013, we announced the initiation of dosing in a Phase 1 clinical trial of APD334, a novel oral drug candidate that targets the sphingosine 1-phosphate subtype 1 (S1P₁) receptor for the potential treatment of autoimmune diseases. This randomized, double-blind and placebo-controlled Phase 1 trial will evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD334 in up to 64 healthy adult volunteers.

About Autoimmune Diseases

Autoimmune diseases 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 tissues, triggering an inflammatory response. Reducing the immune and/or inflammatory response is an important goal in the treatment of autoimmune disease.

About APD334

APD334 is an orally available drug candidate we discovered that targets the S1P₁ receptor for the potential treatment of a number of conditions related to autoimmune diseases, including multiple sclerosis, psoriasis and rheumatoid arthritis. S1P₁ 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. We have optimized APD334 as a potent and selective small molecule S1P₁ receptor agonist that reduces the severity of disease in preclinical autoimmune disease models.

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 advancement, therapeutic indication and use, safety, efficacy, tolerability, selectivity and mechanism of action of APD334; the protocol, design, scope, enrollment and other aspects of the Phase 1 clinical trial of APD334; and the potential of APD334 and treatment of autoimmune diseases in general. 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: APD334 may not have an adequate safety margin or otherwise be sufficient for further development or regulatory review or approval; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the pace of market acceptance; cash and revenues generated from BELVIQ, including the impact of competition; our revenues will be based in part on management's estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding our 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 by any other regulatory agency; 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 safety, efficacy or other regulatory requirements or otherwise be sufficient for further research and development, regulatory review or approval or continued marketing; our ability to obtain and defend patents; the timing, success and cost of our research and development programs; 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: April 5, 2013

Arena Pharmaceuticals, Inc.

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