ARENA PHARMACEUTICALS INC
Form 8-K
April 30, 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): April 29, 2015

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)**	**(I.R.S. Employer 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 April 29, 2015, we announced results from a Phase 1 single-ascending dose clinical trial of APD371, a highly selective and potent agonist of the cannabinoid 2, or CB2, receptor currently in development for the treatment of pain and potentially fibrotic diseases. We believe the results support advancement of APD371 to the next stage of development.

The randomized, double-blind and placebo-controlled Phase 1 clinical trial enrolled 56 healthy adults to evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD371. Dose responsive exposure was observed over the explored dose range of 10-400 mg. APD371 was well tolerated, as evidenced by the lack of dose-limiting adverse events, at drug levels greatly exceeding those anticipated as needed for activating the CB2 receptor.

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, safety, efficacy, mechanism of action and potential of APD371; and the preliminary results of the Phase 1 clinical trial of APD371, including their significance and support for advancing the drug candidate. 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: the 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; APD371 may not be further advanced, 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; the risk that our revenues are 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 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: April 30, 2015

Arena Pharmaceuticals, Inc.

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