ARENA PHARMACEUTICALS INC
Form 8-K
April 12, 2016

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 12, 2016

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

Item 8.01 Other Events.

On April 12, 2016, we announced results from our Phase 1b multiple-ascending dose clinical trial of APD371, a highly selective and potent agonist of the cannabinoid 2, or CB_2, receptor with potential utility in the treatment of pain.

This randomized, double-blind, placebo-controlled Phase 1b clinical trial enrolled 36 healthy adults to evaluate the safety, tolerability and pharmacokinetics of multiple-ascending doses of APD371. Cohorts of 12 subjects (9 active, 3 placebo) were administered doses of 50 mg, 100 mg, or 200 mg of APD371 or placebo three times daily for 10 days and, in connection with the pharmacokinetic evaluation, one time on the 11^{th} day. The most common adverse events were headache and nausea. All adverse events were classified as mild, and there were no serious adverse events reported. There was one discontinuation in the high-dose group due to an adverse event of mild thirst and somnolence. Reductions in blood pressure and heart rate were observed, but none were symptomatic or resulted in an adverse event. Drug levels at all doses tested in the trial, including the lowest dose, were well above those believed to be needed to stimulate the CB_2 receptor.

About APD371

APD371, an orally available agonist of the CB_2 receptor, is our internally discovered investigational drug candidate intended for the treatment of pain and potentially other indications. With its high level of selectivity for the CB_2 receptor versus the CB_1 receptor and its high peripheral restriction observed in preclinical studies, APD371 is designed to provide pain relief without psychotropic effects. Targeting the CB_2 receptor may also avoid or reduce the potential for the dependence or abuse associated with opioid drugs or the adverse event profile associated with NSAIDs. Preclinical efficacy with APD371 has been shown in animal models of osteoarthritic and neuropathic pain.

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, utility, safety, efficacy, selectivity, potency and mechanism of action of APD371; the significance of results from clinical trials and studies of APD371; the potential of APD371 and targeting the CB_2 receptor, including with respect to the treatment of pain and other indications and avoiding or reducing the potential for the dependence, abuse or adverse event profile of other pain treatments; and the dosage level needed to stimulate the CB_2 receptor. 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; APD371 may not provide the anticipated, intended or desired results; APD371 may not be developed, approved for marketing or commercialized for any disease or condition; having adequate funds and other assets and their effective use; risks related to commercializing BELVIQ or any future drug, including regulatory, manufacturing, supply and marketing issues and their availability and use; 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 lorcaserin may not receive any additional marketing approvals; 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; the timing, success and cost of our research and development and related strategy and decisions; 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; 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; and satisfactory resolution of litigation or other disagreements. 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 12, 2016

Arena Pharmaceuticals, Inc.

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