ARENA PHARMACEUTICALS INC
Form 8-K
December 01, 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): November 30, 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., 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® and BELVIQ XR® are registered trademarks of our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

Filing of New Drug Application for BELVIQ XR

On November 30, 2015, Eisai Inc. and we announced that the US Food and Drug Administration, or FDA, has accepted for filing the New Drug Application, or NDA, for an extended release formulation of lorcaserin. If approved, the extended release formulation will offer patients a chronic weight management treatment in a once-daily dosing option.

The regulatory filing for the extended release formulation is based on the results of two Phase 1 registrational clinical trials evaluating bioequivalence of a once-daily, 20 mg extended release formulation of lorcaserin, as compared to the currently approved, twice-daily 10 mg immediate release formulation that is sold under the brand name BELVIQ®. If approved, the extended release formulation is expected to be marketed as BELVIQ XR®, which is the brand name conditionally approved by the FDA.

Update on Enrollment in the CAMELLIA-TIMI 61 Study

On December 1, 2015, Eisai Inc. and we announced that the CAMELLIA-TIMI 61 study has reached its target enrollment of 12,000 patients at more than 470 sites in eight countries. The CAMELLIA-TIMI 61 outcomes study is designed to evaluate the impact of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events and conversion to type 2 diabetes mellitus in obese and overweight patients with cardiovascular disease and/or multiple cardiovascular risk factors.

The CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients) TIMI 61 study is a double-blind, placebo-controlled, parallel-group study, and is being conducted in partnership with the Thrombolysis in Myocardial Infarction, or TIMI, Study Group. The primary safety objective is intended to address the post-marketing requirement from the FDA to evaluate the long-term cardiovascular safety of BELVIQ by evaluating the incidence of major adverse cardiovascular events, or MACE, defined as cardiovascular death, myocardial infarction or stroke. If the primary safety objective is met, the co-primary efficacy objectives are to evaluate the impact of BELVIQ on the incidence of: (1) MACE+, defined as MACE or hospitalization due to unstable angina or heart failure, or any coronary revascularization, and (2) conversion to type 2 diabetes mellitus for subjects without diabetes at baseline. In addition, the study will evaluate the efficacy of BELVIQ with respect to glycemic control in patients with type 2 diabetes mellitus.

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 and potential of BELVIQ, BELVIQ XR or lorcaserin, including the potential of BELVIQ XR to offer once-daily dosing; the potential approval and marketing of an extended release formulation of lorcaserin, including under the brand name BELVIQ XR; the results of the registrational trials of BELVIQ XR, including their support of the NDA for BELVIQ XR; and the cardiovascular outcomes study of BELVIQ, including the protocol, design, scope, enrollment, significance, addressing post-marketing requirements and other expectations. 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 FDA (or any other regulatory agency) may not agree that bioequivalence has been established for BELVIQ XR or ever approve any regulatory application for an extended release formulation of lorcaserin; the cardiovascular outcomes study of BELVIQ may not proceed at all or in the manner or time expected, and the results of the study may not satisfy post-marketing requirements or otherwise be as expected; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and the availability and use of BELVIQ or lorcaserin; cash and revenues generated from BELVIQ; 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; 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 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; 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: December 1, 2015

Arena Pharmaceuticals, Inc.

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