ARENA PHARMACEUTICALS INC
Form 8-K
April 10, 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 7, 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® and BELVIQ XR® are registered trademarks of our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

Lorcaserin Intellectual Property

On April 7, 2015, we and Eisai Inc. announced that the US Patent and Trademark Office granted Arena US Patent No. 8,999,970, which describes a method for selecting appropriate patients based on renal function for BELVIQ (lorcaserin HCl), a serotonin 2C receptor agonist approved for weight management.

We expect this method-of-treatment patent to extend exclusivity for BELVIQ until 2033. In addition to this new patent, composition of matter patents for BELVIQ are issued in major jurisdictions globally that, in most cases, are capable of continuing into 2023. We have filed applications for patent term extension on patents directed to composition of matter in the United States, which, if granted, would extend the composition of matter patent term for BELVIQ into 2026 or potentially 2027.

Eisai Restructuring

On April 9, 2015, Eisai Inc. announced plans to realign its operations in the United States, including reducing its workforce by approximately 25% across various US functions. As part of this restructuring, Eisai has informed us that it will have a new Neurology Sales Force consisting of 90 sales representatives that will promote BELVIQ and two other Eisai products and a shared contract field force of 230 representatives to promote BELVIQ on behalf of Eisai and another product on behalf of another pharmaceutical company.

BELVIQ XR

On April 10, 2015, we and Eisai Inc. announced the completion of two Phase 1 registrational clinical trials that we and Eisai believe demonstrate bioequivalence of an investigational once-daily extended release formulation of lorcaserin, as compared to the twice-daily immediate release formulation approved by the US Food and Drug Administration, or FDA, and marketed as BELVIQ. We plan to submit a New Drug Application for the once-daily extended release formulation with the FDA later this year. If approved, the extended release formulation is expected to be marketed as BELVIQ XR, which is the brand name conditionally approved by the FDA.

Each of the two randomized, crossover trials evaluated the safety, tolerability, pharmacokinetics and bioavailability of an extended release formulation of lorcaserin in 36 healthy adult subjects. Patients in each trial were divided into two treatment groups and received both doses in a two-way crossover sequence. Patients in the first study were dosed under fasted conditions either 10 mg twice-daily, or BID, immediate release or 20 mg once-daily, or QD, extended release. Patients in the second study were dosed either 20 mg QD extended release in the fasted state or 20 mg QD extended release in the fed state.

The most common treatment-emergent adverse events were similar to those seen in the Phase 3 clinical trials of BELVIQ, and included mild or moderate headache, constipation, dizziness and nausea. There were no discontinuations for adverse events, and no serious adverse events were observed.

Lorcaserin extended release formulation is investigational and not approved by any regulatory agency.

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 patent coverage for BELVIQ, including its significance, patent term, exclusivity period and possible extension; the realignment of Eisai s operations; the sales force for BELVIQ, including size and activities; the therapeutic indication, use, safety, efficacy and potential of BELVIQ and BELVIQ XR; submission of a New Drug Application for BELVIQ XR, including related timing; the potential

approval and marketing of the extended release formulation of lorcaserin, including under the brand name BELVIQ XR; and the results of the registrational trials of BELVIQ XR, including their significance. 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 extent, term and significance of patent coverage are uncertain, and any patent may not effectively provide exclusivity against competition or increase the commercial value of a drug; the effectiveness of Eisai s sales and marketing initiatives and related efforts, and whether and how such initiatives and efforts may change in the future; we may determine not to submit a regulatory application for BELVIQ XR or the FDA (or any other regulatory agency) may not accept any such application, agree that bioequivalence has been established or ever approve any such application; 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 10, 2015

Arena Pharmaceuticals, Inc.

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