ARENA PHARMACEUTICALS INC
Form 8-K
January 22, 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): January 22, 2013

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., unless the context otherwise provides.

Item 8.01 Other Events.

In March 2012, we filed a Marketing Authorization Application, or MAA, through the Centralized Procedure with the European Medicines Agency, or EMA, for the marketing approval of BELVIQ® (lorcaserin HCl) in the European Union, or EU. The proposed indication for BELVIQ in the EU is as an adjunct to diet and exercise for weight control in patients over the age of 18 years old who are obese (BMI ³ 30 kg/m2), or are overweight (BMI>27 kg/m2) with associated risk factor(s), such as hypertension, dyslipidemia, cardiovascular disease, type 2 diabetes, or sleep apnea.

We have received the Day 180 List of Outstanding Issues from the EMA s Committee for Medicinal Products for Human Use, or CHMP. The issues will need to be addressed before the CHMP can recommend BELVIQ for marketing approval in the EU. The major objections relate to previously identified non-clinical and clinical issues, including tumors in rats, valvulopathy and psychiatric events, and the CHMP requests that we further justify BELVIQ s overall benefit-risk balance taking these issues into consideration.

In accordance with the CHMP s process, we have been asked to address the issues in writing. The CHMP also plans to consult with independent experts who will provide recommendations on the outstanding issues. In addition to the written response, we have been invited by the CHMP to provide an oral explanation.

The CHMP is expected to reach its final opinion on the BELVIQ MAA by Day 210, which we continue to expect in the first half of 2013.

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, safety, efficacy, EMA marketing approval and potential of BELVIQ; and the EMA regulatory process, including with respect to our responses and other activities, further review and discussions by and between the CHMP, independent experts, us and others, recommendations by independent experts, the CHMP reaching a final opinion and related timing. 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 timing and outcome of regulatory review is uncertain, and BELVIQ may not receive marketing approval from any other regulatory agency or any such approval may include significant limitations on the indicated uses, distribution, marketing and other limitations with respect to BELVIQ; 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; 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: January 22, 2013

Arena Pharmaceuticals, Inc.

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