ARENA PHARMACEUTICALS INC
Form 8-K
May 02, 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): May 2, 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. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2013, we issued a press release reporting our financial results for the first quarter ended March 31, 2013. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

BELVIQ European Union Regulatory Update

We notified the European Medicines Agency, or EMA, that we are withdrawing the BELVIQ (lorcaserin HCl) Marketing Authorization Application, or MAA, in the European Union, and we are currently evaluating the best approach for submitting at a later date

As previously reported, in March 2012, we submitted an MAA through the Centralized Procedure with the EMA, for the marketing approval of BELVIQ in the European Union. We received the Day 180 List of Outstanding Issues from the EMA s Committee for Medicinal Products for Human Use, or CHMP, in January 2013, which identified major objections that needed to be addressed before the CHMP could recommend BELVIQ for marketing approval in the European Union. In accordance with the CHMP s process, we were asked to respond in writing, we were invited by the CHMP to provide an oral explanation, and we expected the CHMP to reach its final opinion at nominal Day 210, which, accounting for anticipated clock stoppages during the regulatory process, we expected to occur in the first half of 2013.

Following our written response to the Day 180 List of Outstanding Issues and our recent oral explanation, the CHMP s view is that certain major objections remain outstanding that preclude a recommendation for approval of the BELVIQ MAA at the present time. We do not believe we can resolve the major objections related to the results of non-clinical studies prior to the time the CHMP would issue its final opinion, and we have, therefore, notified the EMA that we are withdrawing the BELVIQ MAA for the European Union. We are currently evaluating the best approach for submitting at a later date.

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 and efficacy of BELVIQ; the MAA for the marketing approval of BELVIQ in the European Union; the EMA regulatory process; the issues and objections identified by the CHMP, whether or when they can be resolved, and the timing and content of the CHMP s recommendations and final opinion; and withdrawing the BELVIQ MAA and submitting at a later date. 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 EMA s or CHMP s actions, issues, objections, recommendations or opinions may differ from expectations; whether or when we submit for marketing approval in the European Union; regulatory decisions in one territory may impact regulatory decisions in other territories and our business prospects; 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; our revenues will be based in part on management s estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding our 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 when expected or ever by any other regulatory agency; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued May 2, 2013, reporting financial results for the first quarter ended March 31, 2013

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: May 2, 2013

Arena Pharmaceuticals, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued May 2, 2013, reporting financial results for the first quarter ended March 31, 2013