ARENA PHARMACEUTICALS INC
Form 8-K
April 01, 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): April 1, 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 8.01 Other Events.

BELVIQ Regulatory Update

On April 1, 2013, we announced that Eisai Laboratorios S. de R.L. de C.V., a subsidiary of Eisai Inc., has submitted a marketing authorization application, or MAA, for BELVIQ® (lorcaserin HCl) in Mexico with the Federal Commission for the Protection Against Sanitary Risk, or COFEPRIS. The intended indication for BELVIQ is as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of 30 kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. Based on the MAA submission, we will receive a milestone payment of $500,000 from Eisai.

Eisai is responsible for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in Mexico. Subject to approval, we will manufacture BELVIQ at our facility in Switzerland and sell finished commercial product to Eisai for distribution in Mexico. We are eligible to receive payments based upon Eisai s net sales of BELVIQ and also eligible to receive regulatory and development milestone payments.

Legal Proceedings Update

The US District Court for the Southern District of California granted our motions to dismiss (i) a consolidated amended complaint related to purported stockholder class actions and (ii) a complaint involving similar issues brought by an individual stockholder, but gave the plaintiffs until April 25, 2013, to file amended complaints. We cannot predict whether or when amended complaints will be filed, or the ultimate outcome or possible losses relating to these proceedings.

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 advancement, therapeutic indication and use, safety and efficacy of BELVIQ; regulatory filing, review and approval and commercialization of BELVIQ; rights, obligations, expectations and future activities related to the agreement with Eisai; and future activities and developments with respect to litigation. 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: 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.

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 1, 2013

Arena Pharmaceuticals, Inc.

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