

ARENA PHARMACEUTICALS INC
Form 8-K
June 26, 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): June 26, 2013

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-31161
(Commission
File Number)
6154 Nancy Ridge Drive, San Diego, California 92121

23-2908305
(I.R.S. Employer
Identification No.)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

(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 trademark of Arena Pharmaceuticals GmbH, and is registered in the United States and pending in Canada.

Item 8.01 Other Events.

On June 26, 2013, we announced that Eisai Limited (based in Mississauga, Ontario), a subsidiary of Eisai Inc., has submitted a New Drug Submission, or NDS, for BELVIQ (lorcaserin HCl) with Health Canada. BELVIQ is being evaluated in Canada as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management (including weight loss and weight maintenance) in adult obese patients (initial body mass index, or BMI, $\geq 30 \text{ kg/m}^2$), or overweight patients (initial BMI $\geq 27 \text{ kg/m}^2$) in the presence of at least one additional cardiovascular risk factor (e.g., hypertension, dyslipidemia, type 2 diabetes, or sleep apnea).

In connection with the NDS, 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 Canada under its marketing and supply agreement with our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

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, efficacy, tolerability, and regulatory review and approval of BELVIQ; and rights, obligations, milestones, payments, expectations and future activities related to the marketing and supply agreement with Eisai. 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 availability of BELVIQ and 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; regulatory decisions in one territory may impact regulatory decisions in other territories 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 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: June 26, 2013

Arena Pharmaceuticals, Inc.

By: /s/ Jack Lief
Jack Lief
President and Chief Executive Officer