ARENA PHARMACEUTICALS INC
Form 8-K
February 12, 2014

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): February 10, 2014

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 is a trademark of our wholly owned subsidiary, Arena Pharmaceuticals GmbH, and is registered in the United States and pending in Brazil.

Item 8.01 Other Events.

BELVIQ® (lorcaserin HCl) Coverage Update

On February 10, 2014, we reported that Eisai has secured improved patient access of BELVIQ with two leading healthcare benefit companies, and that the estimated number of insured commercial lives in the United States that have coverage for BELVIQ now exceeds 50%.

CVS Caremark customers (employers and health plans) have broadened the coverage of BELVIQ, and eligible CVS Caremark members may have access to BELVIQ in either a preferred or non-preferred brand position depending on the design of the employer benefit or health plan. In addition, Aetna recently announced that it would offer BELVIQ as a preferred brand to eligible patients as part of its pilot program to self-insured plan sponsors nationwide. The Aetna program, which offers access to lifestyle management programs and surgical options, will also measure improvements in health outcomes, productivity and medical costs.

A patient s individual coverage for BELVIQ will vary, and may depend on the design of the patient s employer benefit or health plan. The estimated number of insured commercial lives is derived from Fingertip Formulary data, which is generally based on enrollment reported by health plans and pharmacy benefit managers.

BELVIQ Brazil Filing

On February 12, 2014, we reported that Eisai Laboratorios Ltda., a subsidiary of Eisai Inc., has filed for marketing authorization of BELVIQ as a treatment for chronic weight management with the Brazilian Health Surveillance Agency (Anvisa). In connection with the filing, we will receive a milestone payment of $500,000 from Eisai.

BELVIQ is being submitted for marketing authorization in Brazil as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult obese patients (initial body mass index, or BMI, ³ 30 kg/m^2), or overweight patients (initial BMI ³ 27 kg/m^2) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, cardiovascular disease, type 2 diabetes managed with oral hypoglycemic agents, or sleep apnea).

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, use, safety, efficacy, regulatory review and approval, and potential of BELVIQ; reimbursement coverage of BELVIQ, including the improvement of coverage; CVS Caremark s coverage, the Aetna program and related activities and expectations; and the milestone payment from 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, supply and marketing issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ, including the impact of competition; our revenues will be 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 when expected or ever 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 ability to obtain and defend patents; 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: February 12, 2014

Arena Pharmaceuticals, Inc.

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