ARENA PHARMACEUTICALS INC
Form 8-K
November 03, 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): November 3, 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 registered trademark of our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2014, we issued a press release reporting our financial results for the third quarter ended September 30, 2014. 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.

On November 3, 2014, Eisai Inc. and we announced top-line results from the Phase 2 trial investigating lorcaserin HCl, a serotonin 2C receptor agonist, for smoking cessation. The trial demonstrated statistically significant improvement over placebo in reducing the number of patients who smoke after 12 weeks of treatment. The detailed results of the trial are expected to be presented at a future scientific meeting.

Lorcaserin is an investigational product for smoking cessation. The efficacy and safety of lorcaserin for smoking cessation have not been established.

The 12-week, randomized, double-blind, placebo-controlled trial assessed the efficacy and safety of lorcaserin as a potential aid to smoking cessation. In the trial, 603 active smokers were randomized to receive lorcaserin 10 mg once daily (QD), 10 mg twice daily (BID) or placebo in a 1:1:1 ratio. Patients at baseline were dependent on nicotine and averaged 18 cigarettes per day. Patients were dosed for two weeks before attempting to quit around Day 15 of the trial and received smoking cessation counseling during the trial.

The primary objective of the trial was assessment of smoking cessation efficacy. The carbon monoxide confirmed continuous abstinence rate (CAR), defined as no reported smoking or other nicotine use and an end-expiratory exhaled carbon monoxide measurement of less than or equal to ten parts per million, measured during the last four weeks of the trial (Weeks 9-12), was the basis for determining efficacy. The primary endpoint was achieved by 5.6%, 8.7%, and 15.3% of patients in the placebo, QD and BID groups, respectively (p-value = 0.003 and odds ratio = 3.02 for BID vs. placebo; the result for QD vs. placebo was not statistically significant).

Secondary objectives for the trial included assessment of body weight change and of safety and tolerability. At Week 12 in the MITT population, there was a statistically significant difference in weight between lorcaserin BID and placebo (-0.98 kg and -0.01 kg, respectively, p-value = 0.0004).

The overall adverse event profile appears similar to the profile in previous trials of lorcaserin, with the most common adverse events being headache, nausea, constipation, dizziness and dry mouth.

Eisai and we share the development costs of the smoking cessation development program.

About Lorcaserin for Smoking Cessation

Internally discovered at Arena, lorcaserin is believed to selectively activate serotonin 2C receptors in the brain. Preclinical data suggest that serotonin 2C receptors may modulate the mesolimbic dopaminergic reward system. The exact mechanism of action of lorcaserin is not known.

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, mechanism of action, and potential of BELVIQ or lorcaserin, including as a potential aid for smoking cessation; future presentation of the trial results; and rights, obligations and activities under the marketing and supply agreement among Eisai and us. 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: top-line results are not comprehensive and are based on a preliminary analysis of then available data, and findings and conclusions related to the trial are subject to change following a more comprehensive review of the data; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued November 3, 2014, reporting financial results for the third quarter ended September 30, 2014

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: November 3, 2014

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 November 3, 2014, reporting financial results for the third quarter ended September 30, 2014