ARENA PHARMACEUTICALS INC
Form 8-K
January 13, 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): January 13, 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 South Korea.

Item 8.01 Other Events.

As previously announced, we are scheduled to present a corporate overview today at the 32nd Annual J.P. Morgan Healthcare Conference. The corporate overview will include certain new and updated information as highlighted below.

BELVIQ US Commercialization Update

We previously announced that Eisai planned to increase its BELVIQ® (lorcaserin HCl) sales force to approximately 400 representatives by December 2013, doubling the size of the sales force from when BELVIQ became available in June 2013. The approximately 400 sales representatives are now detailing BELVIQ, which will enable Eisai to reach approximately 65,000 physicians in the United States. Also, BELVIQ is now covered by additional commercial and employer health plans, according to Fingertip Formulary, LLC. While the exact reimbursement coverage for BELVIQ varies by patient, improved access means more patients will receive coverage support from their health plan.

Regulatory Filing in South Korea

Ildong Pharmaceutical Co., Ltd., filed in November 2013 for marketing authorization of BELVIQ as a treatment for chronic weight management with the South Korean Ministry of Food and Drug Safety. BELVIQ was submitted for marketing authorization in South Korea 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, $\geq$ 30 kg/m^2), or overweight patients (initial BMI $\geq$ 27 kg/m^2) in the presence of at least one weight-related comorbid condition.

Lorcaserin for Smoking Cessation

As previously announced, we plan to initiate a Phase 2 clinical trial in the first half of 2014 to evaluate the potential of lorcaserin as a drug candidate for smoking cessation. We expect to enroll approximately 600 patients in this 12-week trial. We and Eisai will share equally the expenses for this trial.

Co-Administration of Lorcaserin and Phentermine

Eisai has initiated dosing in a pilot study of 12-week duration to preliminarily assess as the primary outcome the short-term safety and tolerability of lorcaserin and phentermine when co-administered. This randomized, double-blind and parallel-group study will enroll approximately 225 overweight and obese adults. Patients will be randomized to one of three treatment arms in a 1:1:1 ratio, and will receive lorcaserin 10 mg twice daily, lorcaserin 10 mg twice daily in combination with phentermine 15 mg twice daily, or lorcaserin 10 mg twice daily in combination with phentermine 15 mg once daily. Eisai is responsible for the expenses of this study.

Lorcaserin Extended Release Once-Daily Formulation

We have completed an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of lorcaserin 20 mg extended release tablets to select a once-daily formulation for further development. We and Eisai will share equally the expenses for the development work related to the once-daily formulation.

Lorcaserin Cardiovascular Outcome Trial

Eisai plans to initiate enrollment this month of approximately 12,000 patients in Camellia (**C**ardiovascular **A**nd **M**etabolic **E**ffects of **L**orcaserin **I**n Overweight **A**nd Obese Patients), a cardiovascular outcome trial required by the US Food and Drug Administration, or FDA, as a post-marketing commitment. Camellia is a randomized, double-blind, placebo-controlled trial that will enroll patients with cardiovascular disease or multiple cardiovascular risk factors. The trial is expected to run for approximately five years.

The FDA required portion of the trial is designed to evaluate lorcaserin s effect on the incidence of major adverse cardiovascular events, or MACE, (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. We and Eisai will be responsible for 10% and 90%, respectively, of the expenses for the FDA required portion of the trial.

In addition, Camellia will also evaluate whether lorcaserin reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We and Eisai will share equally the expenses for this non-FDA required portion of the trial up to $40.0 million each, and Eisai will be responsible for 100% of such expenses thereafter.

APD811

We are planning to initiate a Phase 2 clinical trial of APD811, an orally available agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, in the first half of 2014.

APD334

As previously announced, we have completed a Phase 1 clinical trial of APD334, an orally available agonist of the sphingosine 1-phosphate subtype 1, or $S1P_1$, receptor intended for the treatment of a number of conditions related to autoimmune diseases. This randomized, double-blind and placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of single-ascending doses of APD334 in 40 healthy adult volunteers. In the trial, APD334 demonstrated favorable pharmacokinetic and pharmacodynamic effects, a dose-responsive reduction in blood lymphocyte count, and a slowing of heart rate (bradycardia) that appears comparable to other $S1P_1$ agonists. The terminal half-life was approximately 35 hours.

We plan to initiate a Phase 1 multiple-ascending dose trial of APD334 in 2014.

APD371

We initiated dosing in a Phase 1 clinical trial of APD371, an orally available agonist of the cannabinoid-2 receptor intended for the treatment of pain. This randomized, double-blind and placebo-controlled Phase 1 trial will evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD371 in up to 56 healthy adult volunteers.

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 BELVIQ sales force, including their activities, Eisai s physician reach and related expectations; BELVIQ reimbursement coverage, access and support; regulatory review and approval and marketing and distribution of BELVIQ; the advancement, therapeutic indication, use, safety, efficacy or potential of BELVIQ, co-administration of lorcaserin and phentermine, and the drug candidates; selection of a once-daily formulation of lorcaserin; the protocol, design, scope, enrollment, initiation, timing, duration, payment of expenses, results, and other aspects and expectations of studies and trials; and rights, obligations, expectations and future activities related to the marketing and supply agreements with Eisai and Ildong. 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 our collaborator, as applicable, 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: January 13, 2014

Arena Pharmaceuticals, Inc.

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