

ARENA PHARMACEUTICALS INC

Form 8-K

July 14, 2010

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): July 14, 2010

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-31161
(Commission

File Number)

23-2908305
(I.R.S. Employer

Identification No.)

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6166 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, we, us and our refer to Arena Pharmaceuticals, Inc., unless the context otherwise provides.

Item 8.01 Other Events.

On July 14, 2010, we announced that results from the two-year BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial will be published in the July 15, 2010, issue of the *New England Journal of Medicine*. The data presented in the article show that lorcaserin used in conjunction with behavioral modification caused significantly greater weight loss and improved maintenance of weight loss compared to placebo. Lorcaserin also improved values for biomarkers that may be predictive of future cardiovascular events, including lipid levels, insulin resistance, levels of inflammatory markers and blood pressure.

Steven R. Smith, M.D., Scientific Director of the Florida Hospital Translational Research Institute for Metabolism and Diabetes, was the lead author of the article. Neil J. Weissman, M.D., President of MedStar Health Research Institute and Professor of Medicine, Georgetown University, oversaw the echocardiographic safety evaluations that were performed in the study. Drs. Smith and Weissman served as BLOOM's co-principal investigators.

At the end of Year 1 of the BLOOM trial, using Intent-to-Treat with Last Observation Carried Forward analysis, or ITT-LOCF, the proportion of patients achieving at least 5% body weight loss in the lorcaserin group (47.5%) was more than twice that achieved by the placebo group (20.3%). Nearly three times as many patients achieved at least 10% weight loss in the lorcaserin group (22.6%) than in the placebo group (7.7%). Lorcaserin patients who completed the first year of the trial according to the protocol lost an average of 8.2% of their baseline weight, or approximately 18 pounds, at the end of Year 1 as compared to approximately 7 pounds in the placebo group. In Year 2, patients who continued to take lorcaserin were significantly better able to maintain their Year 1 weight loss than those who were switched to placebo.

In Year 1, lorcaserin caused significant decreases in waist circumference, BMI, glycemic parameters, high-sensitivity C-reactive protein, and fibrinogen levels compared to placebo. Total cholesterol, LDL cholesterol and triglyceride levels at Year 1 were significantly lower in the lorcaserin group than in the placebo group. Lorcaserin did not increase heart rate or blood pressure; rather, heart rate, systolic blood pressure and diastolic blood pressure decreased slightly but significantly with lorcaserin treatment compared to placebo. Quality of life, measured by the Impact of Weight on Quality of Life-Lite questionnaire, improved in both treatment groups, with a greater improvement in the lorcaserin group than in the placebo group.

At the end of Year 1, 55.4% of patients in the lorcaserin group and 45.1% of patients in the placebo group remained enrolled in the study, and 7.1% and 6.7% of patients, respectively, discontinued the study due to an adverse event. Among the most frequent adverse events reported with lorcaserin were headache (18.0% vs. 11.0%, lorcaserin vs. placebo); dizziness (8.2% vs. 3.8%); and nausea (7.5% vs. 5.4%). The rates of serious adverse events were similar in both treatment groups. The rates of depression and the incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to placebo in the incidence of new cardiac valvulopathy.

BLOOM Trial Design

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving 3,182 patients in 98 sites in the United States. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance. All patients received diet and exercise counseling, and the trial did not include any dose titration or run-in period. Patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or switch to placebo, and 697 patients on placebo were continued on placebo. Patients underwent echocardiography at screening, and at 6, 12, 18 and 24 months after initiating dosing in the trial; patients with FDA-defined valvulopathy were excluded from enrolling in the trial.

About Lorcaserin

Lorcaserin is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of the serotonin 2C receptor in the hypothalamus is associated with feeding behavior and satiety. We have patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity we might obtain.

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, patent coverage and potential of lorcaserin and significance of biomarkers. 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, risks related to the implementation and continuation of the marketing and supply agreement with Eisai and dependence on Eisai for commercialization of lorcaserin in the United States; regulatory authorities or advisors may not find data from our clinical trials and other studies sufficient for regulatory approval; the timing and our ability to receive regulatory approval for our drug candidates; the ability to enter into agreements to develop or commercialize lorcaserin and other of our compounds or programs; our ability to commercialize lorcaserin outside of the United States with another company or independently; the timing, success and cost of the lorcaserin program and other 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 we or others expect or at all; our ability to obtain adequate funds; our ability to obtain and defend our patents; and the timing and receipt of payments and fees, if any, from Eisai and our collaborators. 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: July 14, 2010

Arena Pharmaceuticals, Inc.

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