ARENA PHARMACEUTICALS INC
Form 8-K
November 12, 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): November 9, 2010

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.)**

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

Item 8.01 Other Events.

On November 9, 2010, we announced that top-line results from the one-year lorcaserin BLOOM-DM trial demonstrate statistically significant weight loss in obese and overweight patients with type 2 diabetes. In this trial, lorcaserin met all three co-primary efficacy endpoints. In addition, as described below, lorcaserin patients taking lorcaserin 10 mg twice daily (BID) achieved statistically significant improvements in multiple secondary endpoints, including HbA1c, as compared to patients randomized to placebo. We also announced that we have requested a meeting with the FDA regarding the Complete Response Letter, or CRL, for lorcaserin, and that the meeting is scheduled to take place before the end of the year.

The BLOOM-DM study evaluated 604 obese and overweight patients with type 2 diabetes. Patients were randomized to lorcaserin 10 mg BID (N=256), lorcaserin 10 mg dosed once daily (QD) (N=95) or placebo (N=253). To expedite enrollment, randomization to the lorcaserin 10 mg QD dose was discontinued after approximately 300 patients were enrolled in the trial.

The three primary efficacy endpoints at Week 52 were as follows: the proportion of patients who lose at least 5% of their baseline body weight; change from baseline in body weight; and the proportion of patients who lose at least 10% of their baseline body weight. Using Modified Intent-to-Treat Last Observation Carried Forward, or MITT-LOCF, analysis, lorcaserin 10 mg BID met the three primary efficacy endpoints by producing statistically significant weight loss compared to placebo ($p<0.0001$). At Week 52, 37.5% of patients treated with lorcaserin 10 mg BID achieved at least 5% weight loss, more than double the 16.1% of patients taking placebo. Patients treated with lorcaserin 10 mg BID achieved mean weight loss of 4.5% (4.7 kg), compared to 1.5% (1.6 kg) for placebo. Also, at Week 52, 16.3% of lorcaserin 10 mg BID patients achieved at least 10% weight loss, compared to 4.4% of patients taking placebo.

BLOOM-DM also evaluated multiple secondary endpoints at Week 52. Five families of endpoints have been or are being evaluated: glycemic, lipid, blood pressure, body composition, and Quality of Life, or QOL. Data from the first three families are available, and analysis of body composition and QOL are pending. Within the glycemic, lipid and blood pressure families, lorcaserin patients achieved statistically significant improvements relative to placebo in HbA1c and fasting glucose. Lorcaserin 10 mg BID patients achieved a 0.9% reduction in HbA1c, compared to a 0.4% reduction for the placebo group ($p<0.0001$). At Week 52, changes with lorcaserin treatment relative to placebo for fasting insulin, triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, and systolic and diastolic blood pressure were not statistically significant.

BLOOM-DM Safety Results

The most frequent adverse events occurring in greater than or equal to 10% of patients (excluding hypoglycemia) and the proportion of patients affected for lorcaserin 10 mg BID and placebo, respectively, were as follows: headache (14.5%, 7.1%), upper respiratory infection (13.7%, 14.7%), back pain (11.7%, 7.9%) and nasopharyngitis (11.3%, 9.9%). Headache and hypoglycemia were the only adverse events that exceeded the placebo rate by greater than 4% of

patients. Adverse events of hypoglycemia, which included asymptomatic low blood glucose measurements and symptomatic events, were reported by 29.3% and 21.0% of lorcaserin 10 mg BID and placebo patients, respectively; however, no events of severe hypoglycemia were reported in either treatment group. Serious adverse events were infrequent.

The Week 52 completion rates were higher for patients taking lorcaserin 10 mg BID (66.0%) compared to patients taking placebo (62.1%). Discontinuations for adverse events were 8.6% for lorcaserin 10 mg BID patients and 4.3% for placebo patients.

Echocardiograms were performed at baseline and at Weeks 24 and 52. At Week 24, 2.5% (five) of lorcaserin 10 mg BID patients and 1.9% (four) of placebo patients had new valvulopathy (based on FDA criteria), and at Week 52, 2.9% (six) of lorcaserin 10 mg BID patients and 0.5% (one) of placebo patients had new valvulopathy. BLOOM-DM was not powered to detect meaningful differences in the incidence of valvulopathy.

Baseline Patient Characteristics

BLOOM-DM evaluated obese and overweight patients with type 2 diabetes treated with one or more oral anti-hyperglycemic agents. At baseline, patients had an average Body Mass Index, or BMI, of 36, weight of 228 pounds (103.6 kg), age of 53 years, and HbA1c of approximately 8%. Proportions of Caucasian, African American and Hispanic patients were 61%, 21% and 14%, respectively, and 54% of patients were female.

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 BLOOM-DM; the advancement, therapeutic indication and use, safety, efficacy, tolerability, mechanism of action, and regulatory review of lorcaserin; and meeting with the FDA regarding the CRL for lorcaserin. 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, top-line results are based on a preliminary analysis of then available data, and such findings and conclusions are subject to change following a more comprehensive review of the data; the risk that regulatory authorities may not find data and other information related to our clinical trials and other studies meet safety or efficacy requirements or are otherwise sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; our response to the CRL for the lorcaserin NDA may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request additional information prior to approval; unexpected new data; risks related to commercializing new products; our ability to obtain and defend our 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 we or others expect or at all; our ability to obtain adequate funds; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from our collaborators; and satisfactory resolution of pending and any future 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: November 11, 2010

Arena Pharmaceuticals, Inc.

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