ARENA PHARMACEUTICALS INC
Form 8-K
May 26, 2011

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): May 26, 2011

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 May 26, 2011, we presented meta-analyses of the three trials in our lorcaserin Phase 3 clinical trial program at ECO 2011, the 18th European Congress on Obesity. The analyses show that lorcaserin caused statistically significant weight loss compared to placebo at one year among 7,500 obese and overweight, diabetic and non-diabetic adults. The lorcaserin-mediated weight loss was associated with favorable changes in biomarkers that may be predictive of cardiovascular and metabolic risk and in quality of life.

At one year, using Modified Intent-to-Treat with Last Observation Carried Forward analysis, or MITT-LOCF, of the integrated results, 46.3% of lorcaserin 10 mg twice daily, or BID, patients and 40.6% of lorcaserin 10 mg once daily, or QD, patients achieved at least 5% weight loss, compared to 22.1% of patients on placebo, and 22.0% of lorcaserin 10 mg BID patients and 17.3% of lorcaserin 10 mg QD patients achieved at least 10% weight loss, compared to 8.3% of patients on placebo. Of the patients completing year one of the trials, 62.3% of lorcaserin 10 mg BID patients and 52.8% of lorcaserin 10 mg QD patients achieved at least 5% weight loss, compared to 32.0% of patients on placebo, and 33.5% of lorcaserin 10 mg BID patients and 25.5% of lorcaserin 10 mg QD patients achieved at least 10% weight loss, compared to 13.8% of patients on placebo. Notably, this meta-analysis included approximately 600 patients enrolled with type 2 diabetes, a disease that typically makes weight loss more difficult to achieve.

Changes in secondary endpoints of cardiovascular and metabolic risk were assessed in the Phase 3 program. Body Mass Index, or BMI, waist circumference, triglycerides, total cholesterol, LDL cholesterol, HDL cholesterol, systolic blood pressure, diastolic blood pressure, heart rate and quality of life were measured in all three trials in the Phase 3 program, and the integrated Year 1 results showed favorable statistically significant effects with lorcaserin 10 mg BID treatment compared to placebo. Lorcaserin did not increase heart rate or blood pressure; changes from baseline for patients who took lorcaserin 10 mg BID, lorcaserin 10 mg QD or placebo, respectively, were as follows: systolic blood pressure (mmHg), (-0.9, -0.2, -0.2); diastolic blood pressure (mmHg), (-1.4, -0.5, -0.8); and heart rate (bpm), (-1.0, -0.5, -0.2).

The most frequent lorcaserin-associated adverse events included headache, nausea, dizziness, fatigue and dry mouth. Headache was the only adverse event with an incidence that exceeded the placebo group by greater than 5%. In each trial, echocardiograms were performed at baseline and every six months to measure heart valve regurgitation. In the meta-analysis of the three trials, the proportion of patients who developed FDA-defined valvulopathy (moderate or greater mitral insufficiency and/or mild or greater aortic insufficiency) at Week 52 were as follows: lorcaserin 10 mg BID (2.37%), lorcaserin 10 mg QD (1.57%) and placebo (2.04%).

The three lorcaserin Phase 3 trials randomized a total of 7,794 patients, and 7,500 patients were included in the primary efficacy analyses (MITT-LOCF), which required a patient to have taken at least one dose of study medication and have had at least one weight measurement subsequent to baseline. The MITT-LOCF analyses included 3,349 lorcaserin 10 mg BID patients, 865 lorcaserin 10 mg QD patients and 3,286 placebo patients. Patients had an average BMI, baseline weight and age of approximately 36 kg/m^2, 100 kg and 45 years, respectively; approximately 80% 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 the therapeutic indication and use, safety, efficacy, tolerability, mechanism of action and potential of lorcaserin; and the 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, the following: the timing of regulatory review and approval is uncertain; the risk that data and other information related to our research and development programs, including for lorcaserin, may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; our response to the CRL for the lorcaserin NDA may not be submitted when anticipated, if at all; the FDA may request other information prior to or after we submit such response or approval of the lorcaserin NDA; unexpected or unfavorable 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 expected 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 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: May 26, 2011

Arena Pharmaceuticals, Inc.

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