ARENA PHARMACEUTICALS INC
Form 8-K
June 24, 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): June 24, 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.

We are scheduled to present additional data and analyses from our Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial at the American Diabetes Association s (ADA) 71st Scientific Sessions on June 26 and June 27, 2011. A summary of the BLOOM-DM results is provided below.

As previously announced, obese and overweight patients with type 2 diabetes who were treated with lorcaserin 10 mg dosed twice daily achieved statistically significant categorical and absolute weight loss and improvements in HbA1c and fasting plasma glucose at one year as compared to patients taking placebo, using Modified Intent-to-Treat Last Observation Carried Forward (MITT-LOCF) analysis:

- 37.5% of lorcaserin patients lost at least 5% of their body weight, compared to 16.1% for placebo ($p<0.0001$). As with BLOOM and BLOSSOM, this result satisfies one of two alternate efficacy benchmarks in the most recent US Food and Drug Administration (FDA) draft guidance for weight-management products, which provides that a weight-management product can be considered effective if after one year of treatment the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.

- Lorcaserin patients achieved a least squares mean (LS mean) weight loss of 4.5%, or 10.3 pounds, compared to 1.5%, or 3.5 pounds, for placebo. ($p<0.0001$)

- 16.3% of lorcaserin patients lost at least 10% of their body weight, compared to 4.4% for placebo. ($p<0.0001$)

- Lorcaserin patients achieved a 0.9% reduction in HbA1c, compared to a 0.4% reduction for placebo. ($p<0.001$)

- Lorcaserin patients achieved a 27.4 mg/dL reduction in fasting plasma glucose, compared to an 11.9 mg/dL reduction for placebo. ($p<0.001$)

In addition to the previously announced data, the following results will be presented in poster sessions at the ADA Scientific Sessions:

- At baseline, 8% of patients had HbA1c <7%; at Week 52, 50.4% of lorcaserin patients, compared to 26.3% of placebo patients had HbA1c <7%. (MITT-LOCF, $p<0.001$)

- Lorcaserin patients achieved statistically significant improvement in LS mean HbA1c compared to placebo at Week 12, and the improvement was maintained through Week 52. (MITT-LOCF, $p<0.0001$)

Patients who completed the one-year trial were evaluated and achieved the following results:

44.6% of lorcaserin patients lost at least 5% of their body weight, compared to 17.9% for placebo. ($p<0.0001$)

Lorcaserin patients achieved LS mean weight loss of 5.5%, or 12.0 pounds, compared to 1.7%, or 3.8 pounds, for placebo. ($p<0.0001$)

20.8% of lorcaserin patients lost at least 10% of their body weight, compared to 5.8% for placebo. ($p<0.0001$)

Lorcaserin patients achieved a 1.0% reduction in HbA1c, compared to a 0.5% reduction for placebo. ($p<0.001$)

Lorcaserin patients achieved a 28.4 mg/dL reduction in fasting plasma glucose, compared to a 12.4 mg/dL reduction for placebo. ($p<0.001$)

At baseline, approximately 90% of patients were taking metformin and approximately 50% of patients were taking sulfonylureas with or without metformin. Weight loss and reductions in HbA1c and fasting plasma glucose were greater with lorcaserin treatment compared to placebo whether patients were treated with metformin or sulfonylureas. Fewer patients on lorcaserin compared to placebo (13.5% vs. 22.2%, respectively) increased and more patients on lorcaserin compared to placebo (17.1% vs. 11.7%, respectively) decreased use of anti-diabetic medication during the study.

Safety and Tolerability Profile

The most frequent adverse events and their incidences for lorcaserin 10 mg twice daily and placebo patients, respectively, were as follows: headache (14.5% vs. 7.1%), upper respiratory tract infection (13.7% vs. 14.7%), back pain (11.7% vs. 7.9%), nasopharyngitis (11.3% vs. 9.9%) and symptomatic hypoglycemia (7.4% vs. 6.3%). Adverse events were similar to those in patients without type 2 diabetes, with the exception of hypoglycemia.

The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (66.0%) compared to patients on placebo (62.1%). Discontinuation rates for adverse events were as follows: lorcaserin 10 mg twice daily (8.6%) and placebo (4.3%); and the incidences of serious adverse events were as follows: lorcaserin (6.3%) and placebo (6.7%).

Echocardiograms were used to evaluate the possible association between lorcaserin and cardiac valvular insufficiency. The proportions of patients who developed new FDA-defined valvulopathy in BLOOM-DM were as follows: lorcaserin 10 mg twice daily (2.5%) and placebo (1.9%) at Week 24, and lorcaserin 10 mg twice daily (2.9%) and placebo (0.5%) at Week 52. By design, BLOOM-DM enrolled too few patients to independently detect meaningful differences in the incidence of valvulopathy with adequate statistical power. We expect the FDA will consider the BLOOM-DM safety and efficacy data in combination with BLOOM, BLOSSOM and other data and information in our planned response to the lorcaserin complete response letter.

Patient Demographics and Disposition, Enrollment and Randomization

BLOOM-DM evaluated 604 obese and overweight patients with type 2 diabetes and an average BMI of 36 kg/m^2 and baseline weight of 228 pounds. The average age was 53 years, and 54% of the patients were women. Most patients were Caucasian (61%), African-American (21%) or Hispanic (14%). Patients were randomized to lorcaserin 10 mg twice daily (N=256), lorcaserin 10 mg dosed once daily (N=95) or placebo (N=253). To expedite enrollment, randomization to the lorcaserin 10 mg once daily dose was discontinued after approximately 300 patients were enrolled in the trial. Patients in the low dose group were continued in the trial to maintain the blind, but this group was recruited over a different time period and from a different spectrum of study sites. As a result, we believe there are limitations on comparing the results of the low dose group to the other two groups.

Forward-Looking Statements

Certain statements in this press release 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, regulatory review and expectations regarding lorcaserin; the response to the CRL for the lorcaserin NDA; and BLOOM-DM data, including the alignment of its efficacy results with the FDA s categorical benchmark for weight management and the FDA s consideration of such data in combination with other studies. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena s 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 Arena s research and development programs, including for lorcaserin, may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; Arena s response to the CRL for the lorcaserin NDA or submission of a Marketing Authorization Application for regulatory approval of lorcaserin may not be submitted when anticipated, if at all; the FDA may request other information prior to or after Arena submits such response or approval of the lorcaserin NDA; unexpected or unfavorable new data; risks related to commercializing new products; Arena s ability to obtain and defend its patents; the timing, success and cost of Arena s 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; Arena s 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 Arena s forward-looking statements are disclosed in Arena s filings with the Securities and Exchange Commission. These forward-looking statements represent Arena s judgment as of the time of this release. Arena disclaims 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: June 24, 2011

Arena Pharmaceuticals, Inc.

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