ARENA PHARMACEUTICALS INC
Form 8-K
October 03, 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): October 3, 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 October 3, 2011, we presented new data analyses from our lorcaserin Phase 3 clinical trial program at Obesity 2011, the 29th Annual Scientific Meeting of The Obesity Society.

***- Effects of Lorcaserin, a Selective Serotonin 2C Agonist, on Cardiac Valvular Regurgitation in Obese and Overweight Patients During Exposures up to Two Years Presenting Authors: Neil J. Weissman, M.D.,***

President of MedStar Health Research Institute and Professor of Medicine, Georgetown University; and Christen M. Anderson, M.D., Ph.D., Arena s Vice President, Lorcaserin Development

We previously announced the incidences of FDA-defined valvulopathy (which is mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation) among patients taking lorcaserin 10 mg dosed twice daily, or BID, and patients taking placebo in the lorcaserin Phase 3 clinical trial program. As presented below, a number of additional analyses were performed to assess the effect of lorcaserin on cardiac valvular regurgitation.

In each trial of the lorcaserin Phase 3 clinical program BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) echocardiograms were performed at baseline and every six months to measure heart valve regurgitation. The trial designs entailed combining data from all three trials to provide a sufficient number of patients to rule out a 50% or greater increase in risk of FDA-defined valvulopathy at Week 52 in patients taking lorcaserin as compared to patients taking placebo, with ³ 80% statistical power.

The proportions of patients who developed FDA-defined valvulopathy at Week 52 in the three trials were as follows: lorcaserin 10 mg BID (2.37%; N=2,696) and placebo (2.04%; N=2,553). All identified valvulopathy was limited to incidental echocardiographic findings; no patient with FDA-defined valvulopathy had clinical signs or symptoms.

The primary pre-specified statistical analysis was a test of the difference in proportions between placebo and lorcaserin using Modified Intent-to-Treat, Last Observation Carried Forward (MITT-LOCF) analysis, relative to a non-inferiority margin of 1.25% (50% of the assumed placebo proportion of 2.5%). According to this primary analysis of risk difference, lorcaserin 10 mg BID was non-inferior to placebo.

Point estimates for relative risk of FDA-defined valvulopathy associated with lorcaserin treatment were 1.03 (completers, 95% confidence interval: 0.68, 1.57) and 1.16 (MITT-LOCF, 95% confidence interval: 0.81, 1.67) at Week 52. Using additional statistical analyses that included all available echocardiograms over up to two years of exposure to lorcaserin, the risk or hazard ratios ranged from 1.08 to 1.09, with the upper bound of the 95% confidence intervals less than 1.5.

**Association Between Valvulopathy and Change in BMI and Body Weight**

An analysis of echocardiographic data from the Framingham Offspring Study (Singh et al., *Am J Cardiol* 1999; 83: 897-902) showed that the apparent prevalence of mitral regurgitation was inversely related to Body Mass Index, or BMI that is, obese individuals tended to have a lower prevalence of significant mitral regurgitation than non-obese individuals. To determine whether changes in BMI or body weight in the lorcaserin trials were associated with changes in apparent incidence of valvulopathy, the pooled placebo echocardiographic data alone and the pooled placebo and lorcaserin echocardiographic data were separately analyzed. Changes in BMI and body weight were negatively associated with FDA-defined valvulopathy regardless of treatment group, and the statistical modeling projected that:

Each 2 $kg/m^2$ decrease in BMI will increase apparent incidence of FDA-defined valvulopathy by 1.16 times

Each 5% decrease in body weight will increase apparent incidence of FDA-defined valvulopathy by 1.15 times

These findings predict that the incidence of valvulopathy as measured by echocardiography will increase slightly with decreased BMI or body weight. It is possible that decreases in BMI or body weight allow for better quality echocardiographic images in which regurgitant flow is easier to detect.

***- Lorcaserin Reduced Weight and Improved Glycemic Control Across Patient Subgroups in Patients with Type 2 Diabetes***

Presenting Author: Brian L. Raether, Arena s Senior Clinical Project Manager, Clinical Operations

BLOOM-DM evaluated 604 obese (BMI ³30) and overweight (BMI ³27) patients with type 2 diabetes over a one-year treatment period. The data were analyzed to determine whether baseline characteristics affected the response to lorcaserin.

Overall using MITT-LOCF analysis, 37.5% of lorcaserin 10 mg BID patients lost at least 5% of their body weight, compared to 16.1% for placebo; lorcaserin 10 mg BID patients achieved a 0.9% reduction in HbA1c, compared to a 0.4% reduction for placebo, and a 27.4 mg/dL reduction in fasting plasma glucose, compared to an 11.9 mg/dL reduction for placebo. The data show that patients who took lorcaserin 10 mg BID achieved greater reductions in body weight, HbA1c and fasting plasma glucose than the placebo group in all subgroups evaluated, as defined by gender, age, ethnicity and baseline HbA1c and BMI.

The lorcaserin plasma concentrations (ng/mL) at Week 12 were similar across subgroups. The adverse event profiles were also similar across subgroups; the most frequent lorcaserin-associated adverse events (defined as events occurring in at least 5% of lorcaserin patients and at least 1.5 times the placebo incidence) included headache, urinary tract infection, cough, viral gastroenteritis, fatigue, hypertension and procedural pain.

***- Safety and Efficacy of Lorcaserin: Comparison of Diabetic and Non-diabetic Patient Populations***

Presenting Author: Scott C. Stubbe, Arena s Associate Director, Clinical Operations

In the lorcaserin Phase 3 clinical trial program, BLOOM and BLOSSOM enrolled a total of 7,190 non-diabetic patients who were obese or who were overweight and had at least one weight-related co-morbid condition, and BLOOM-DM enrolled 604 obese and overweight patients with type 2 diabetes. The data were analyzed to evaluate the effect of lorcaserin treatment (10 mg BID) in a non-diabetic patient population compared to patients with type 2 diabetes, a disease that typically makes weight loss more difficult to achieve.

On average at baseline, the patients with type 2 diabetes were older than non-diabetic patients (52.6 years versus 44.0 years, respectively), weighed more (103.0 kg versus 100.3 kg, respectively) and included more men (46.0% versus 18.6%, respectively). Both groups had an average BMI of 36 $kg/m^2$. Study completion rates were 64% for patients with type 2 diabetes and 53% for non-diabetic patients.

Lorcaserin was associated with statistically significant weight loss compared to placebo in patients with or without type 2 diabetes. At Week 52 (MITT-LOCF), 47.1% of non-diabetic patients taking lorcaserin 10 mg BID lost at least 5% of their body weight, compared to 22.6% of non-diabetic placebo patients, and 37.5% of patients with type 2 diabetes taking lorcaserin 10 mg BID lost at least 5% of their body weight, compared to 16.1% for placebo patients with type 2 diabetes.

Mean weight loss (MITT-LOCF) at Week 52 was 5.8% for non-diabetic patients taking lorcaserin 10 mg BID, compared to 2.5% for non-diabetic placebo patients, and 4.8% for patients with type 2 diabetes taking lorcaserin 10 mg BID, compared to 1.8% for placebo patients with type 2 diabetes. Among study completers, mean weight loss was 8.0% for non-diabetic patients taking lorcaserin 10 mg BID, compared to 3.7% for non-diabetic placebo patients, and 5.8% for patients with type 2 diabetes taking lorcaserin 10 mg BID, compared to 2.1% for placebo patients with type 2 diabetes.

A larger proportion of patients with type 2 diabetes had dyslipidemia and/or hypertension upon entering the study than did the non-diabetic patients. Nevertheless, trends in lipids and body fat loss were similar among the diabetic and non-diabetic patient populations. Treatment with lorcaserin 10 mg BID was not associated with increases in blood pressure or heart rate in either diabetic or non-diabetic patients; rather, statistically significant decreases occurred in the non-diabetic group.

Lorcaserin treatment was not associated with an increase in depression in either patient population and lorcaserin-related adverse events were similar among the diabetic and non-diabetic patient populations, with the exception of symptomatic hypoglycemia (which occurred in 7.4% of patients with type 2 diabetes taking lorcaserin 10 mg BID, compared to 6.3% of placebo patients with type 2 diabetes, and 0.1% in non-diabetic patients taking lorcaserin 10 mg BID, compared to 0% of non-diabetic placebo patients). The most frequent lorcaserin-associated adverse events (defined as events occurring in greater than 5% of lorcaserin patients and at least 1.5 times the placebo incidence) among the non-diabetic population included headache, dizziness, nausea, fatigue and dry mouth. The profile among patients with type 2 diabetes was similar, although dizziness and nausea occurred at only 1.1 and 1.2 times the placebo incidence, respectively. Headache was the only adverse event in either the diabetic or non-diabetic population with an incidence that exceeded the placebo group by greater than 5%.

**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 association between valvulopathy and change in BMI and body weight and related predictions and analyses. 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: regulatory agencies may interpret and analyze the data differently and may reach different conclusions; the timing of regulatory review and approval is uncertain; the risk that data and other information related to our research and development programs may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; our 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 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: October 3, 2011

Arena Pharmaceuticals, Inc.

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

Secretary