ARENA PHARMACEUTICALS INC
Form 8-K
March 30, 2009

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): March 30, 2009

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)**

Registrant s telephone number, including area code: 858.453.7200

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. and its wholly owned subsidiaries, unless t context otherwise provides.

Item 8.01 Other Events.

On March 30, 2009, we announced positive top-line results from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management. Statistical significance ($p<0.0001$) was achieved on all three of the hierarchically ordered co-primary endpoints for patients treated with lorcaserin versus placebo. Treatment with lorcaserin was generally very well tolerated. An assessment of echocardiograms indicates no apparent drug-related effect on the development of US Food and Drug Administration (FDA)-defined valvulopathy over the two-year treatment period.

Primary Endpoint Analysis

The hierarchically ordered endpoints were the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Compared to placebo, using an intent-to-treat last observation carried forward (ITT-LOCF) analysis, treatment with lorcaserin was associated with highly statistically significant ($p<0.0001$) categorical and average weight loss from baseline after 12 months:

- 47.5% of lorcaserin patients lost greater than or equal to 5% of their body weight from baseline compared to 20.3% in the placebo group. This result satisfies the efficacy benchmark in the most recent FDA draft guidance.
- Average weight loss of 5.8% of body weight, or 12.7 pounds, was achieved in the lorcaserin group, compared to 2.2% of body weight, or 4.7 pounds, in the placebo group. Statistical separation from placebo was observed by Week 2, the first post-baseline measurement.
- 22.6% of lorcaserin patients lost greater than or equal to 10% of their body weight from baseline, compared to 7.7% in the placebo group.

Lorcaserin patients who completed 52 weeks of treatment according to the protocol lost an average of 8.2% of body weight, or 17.9 pounds, compared to 3.4%, or 7.3 pounds, in the placebo group ($p<0.0001$).

Safety and Tolerability Profile

Lorcaserin was generally very well tolerated. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%) and nausea (7.5% vs. 5.4%). The most frequent adverse events reported in Year 2 and their rates for lorcaserin and placebo patients, respectively, were as follows: upper respiratory tract infection (14.5% vs. 16.1%), nasopharyngitis (16.4% vs. 12.6%), sinusitis (8.6% vs. 6.9%), arthralgia (6.6% vs. 6.2%) and influenza (6.6% vs. 6.0%). In patients crossing over from lorcaserin to placebo after Year 1, the rates of these Year 2 adverse events were: 11.0%, 13.8%, 10.6%, 6.0% and 4.9%, respectively.

Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group, and no seizures were reported. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to lorcaserin. One death occurred during the trial, which was a patient in the placebo arm.

Echocardiogram Assessment

Using an ITT-LOCF analysis, the assessment of echocardiograms performed at baseline and after patients completed 6, 12, 18 and 24 months of dosing indicated no apparent drug-related effect on the development of FDA-defined valvulopathy (moderate or greater mitral insufficiency and/or mild or greater aortic insufficiency).

Lorcaserin met the primary safety endpoint of no significant difference in rates of valvulopathy at 12 months. Rates of valvulopathy at 6, 12, 18 and 24 months for lorcaserin versus placebo were 2.1% vs. 1.9%, 2.7% vs. 2.3%, 2.9% vs. 3.1% and 2.6% vs. 2.7%. At 18 and 24 months, rates of valvulopathy for lorcaserin patients crossing over to placebo were 3.6% and 1.9%, respectively.

The FDA has requested that we rule out a 1.5-fold or greater risk of valvulopathy with 80% power. Assuming similar results in BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management), the integrated data set from the two trials will be more than sufficiently large to meet this requirement.

Secondary Endpoint Analysis

Treatment with lorcaserin was also associated with statistically significant improvements (ITT-LOCF) in a range of secondary endpoints compared to treatment with placebo, including:

- Total cholesterol
- LDL cholesterol
- Triglycerides
- Blood pressure

Changes in HDL cholesterol were similar in the two groups. Analysis of the above and additional endpoints, including glucose, insulin and waist circumference, is ongoing and will be announced at a later date.

During Year 2 of the trial, patients continuing on lorcaserin were better able to maintain more of the Week 52 weight loss than Year 1 lorcaserin patients re-randomized to placebo in Year 2.

Patient Disposition

Patient demographic characteristics at baseline were well balanced across the treatment groups. The Week 52 completion rate was higher for patients on lorcaserin (55.4%) compared to those on placebo (45.1%). The difference is primarily attributed to higher discontinuation rates for Subject Decision (19.2% lorcaserin vs. 27.7% placebo), which includes Lack of Efficacy (1.7% lorcaserin vs. 5.5% placebo). Discontinuations for adverse events (7.1% lorcaserin vs. 6.7% placebo) and other reasons were similar.

Completion rates for Year 2 were similar across the treatment groups: 74.3%, 72.7%, and 68.9% for patients continuing on lorcaserin for both years, patients taking placebo both years, and patients switching from lorcaserin to placebo in Year 2, respectively. Discontinuations for adverse events were also similar across the treatment groups.

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 approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, or 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. 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 to switch to placebo, and 697 patients on placebo were continued on placebo. Patients received echocardiograms 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.

Phase 3 Program Overview

The Phase 3 program consists of three trials, BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), and is planned to enroll a total of approximately 7,800 patients. BLOOM and BLOSSOM

comprise the Phase 3 pivotal registration program. BLOSSOM has enrolled 4,008 patients and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 sites in the US. Results are expected around the end of September 2009. BLOOM-DM is currently enrolling and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US. Approximately 600 patients are expected to be enrolled in BLOOM-DM, which is planned as a supplement to the lorcaserin NDA.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program s hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. We are also studying several key secondary endpoints, including changes in serum lipids and HbA1c levels and, in the BLOOM-DM trial, other indicators of glycemic control. In BLOSSOM and BLOOM-DM all patients will receive echocardiograms at baseline, at month 6, and at the end of the study to assess heart valve function over time. In contrast to the BLOOM trial, however, there are no echocardiographic exclusion criteria for entry into these trials and there is no monitoring by an independent monitoring board.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is located in areas of the brain involved in the control of appetite and metabolism, such as the hypothalamus. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Lorcaserin is currently being evaluated in a Phase 3 program expected to enroll approximately 7,800 patients and potentially represents a targeted treatment option for the millions of patients who need to better manage their weight. We have patents that cover lorcaserin in the US 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.

About the FDA Draft Guidance

The FDA draft guidance document for developing products for weight management dated February 2007 provides recommendations regarding the development of drugs for the indication of weight management. It contains two alternate efficacy benchmarks. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of subjects who lose greater than or equal to 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.

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 development, therapeutic indication, tolerability, safety, selectivity, efficacy and potential of lorcaserin; the significance of the review of echocardiographic data and lorcaserin s effect on the development of FDA-defined valvulopathy; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the continued advancement of the related program; the significance of the BLOOM results; future activities, results and announcements relating to lorcaserin; the potential of lorcaserin to meet the FDA s requirements for approval and the approval of lorcaserin for marketing; commercialization options and the coverage of lorcaserin patents; and about our strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. 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, our ability to obtain additional funds, the timing, success and cost of our lorcaserin program and other of our research and development programs, the results of clinical trials or preclinical studies may not be predictive of future results, clinical trials and studies may not proceed at the time or in the manner we expect or at all, our ability to partner lorcaserin or other of our compounds or programs, the timing and ability of us to receive regulatory approval for our drug candidates, our ability to obtain and defend our patents, and the timing and receipt of payments and fees, if any, from 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 other filings with the Securities and Exchange Commission. These forward-looking statements represent our judgment as of the time of the filing of this 8-K. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

SIGNATURES

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: March 30, 2009

Arena Pharmaceuticals, Inc.

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

Counsel and Secretary