ARENA PHARMACEUTICALS INC
Form 8-K
June 08, 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): June 6, 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)

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, we, us and our refer to Arena Pharmaceuticals, Inc., and its wholly owned subsidiaries, unless context otherwise provides.

Item 8.01 Other Events.

On June 6, 2009, we announced a late-breaking poster presentation of positive 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, at the American Diabetes Association s 69th Scientific Sessions. Lorcaserin patients achieved highly significant categorical and absolute weight loss in Year 1, and continued treatment with lorcaserin in Year 2 helped significantly more patients maintain their weight loss as compared to those on placebo. Treatment with lorcaserin also resulted in highly significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin did not result in increased risk of depression and was not associated with the development of cardiac valvular insufficiency.

Previously announced BLOOM data demonstrated that lorcaserin was highly efficacious, achieving statistical significance on all three co-primary efficacy endpoints, and was very well tolerated. The BLOOM results also satisfy the efficacy requirement in the most recent US Food and Drug Administration, or FDA, draft guidance for the development of drugs for weight management.

Per Protocol Efficacy

In addition to supporting the previously announced results on all three co-primary endpoints on an intent-to-treat, last observation carried forward (ITT-LOCF) basis, the data presented on June 6, 2009 demonstrated strong efficacy in patients who completed one year of treatment according to the trial s protocol. In the per protocol population, nearly two-thirds (66.4%) of lorcaserin patients lost at least 5% of their weight compared to 32.1% of patients on placebo ($p<0.0001$), and over one-third (36.2%) of lorcaserin patients lost at least 10% of their weight compared to 13.6% for placebo ($p<0.0001$). The average weight loss in this population was 17.9 pounds in the lorcaserin group, compared to 7.4 pounds in the placebo group. Patients randomized to remain on lorcaserin for Year 2 maintained a significantly greater amount of weight loss compared to the lorcaserin patients who switched to placebo at Week 52 in both the ITT-LOCF and per protocol populations.

Secondary Endpoint Analysis

New data demonstrate that treatment with lorcaserin over one year was associated with highly significant improvements compared to placebo in multiple secondary endpoints associated with cardiovascular risk, including:

Blood Pressure: systolic blood pressure, diastolic blood pressure and heart rate

Lipids: total cholesterol, LDL cholesterol and triglycerides

Glycemic Parameters: fasting glucose, fasting insulin and insulin resistance

Inflammatory Markers of Cardiovascular Risk: high-sensitivity CRP and fibrinogen

Quality of Life, as assessed by the Impact of Weight Questionnaire Lite, also improved to a significantly greater extent in the lorcaserin group than the placebo group at Week 52.

Safety and Tolerability Profile

Lorcaserin was very well tolerated. Discontinuation rates for adverse events were similar in the lorcaserin and placebo groups for Year 1 and Year 2 (7.1% vs. 6.7% and 3.0% vs. 3.0%, respectively).

In addition to the previously announced tolerability data, the June 6, 2009 presentation also reported that lorcaserin demonstrated no increase in depression or suicidal ideation compared to placebo. Depression adverse events were measured using a Standard MedDRA Query for adverse event terms related to depression (e.g. depression, depressed mood, crying, decreased interest, etc.). Overall, the rate of depression-related events was low and rates were comparable in patients who took lorcaserin and placebo. Suicidal ideation was prospectively evaluated by administration of the Beck Depression Inventory-II. Overall, the rate of suicidal ideation was low and similar numbers of patients on lorcaserin and placebo reported suicidal thoughts during Year 1 and Year 2.

Cardiovascular Safety

Using an LOCF analysis for each year, the assessment of echocardiograms performed at baseline and after patients completed 6, 12, 18 and 24 months of dosing indicated that lorcaserin was not associated with valvular insufficiency: during two years of use, rates of change in individual regurgitant scores and the development of FDA-defined valvulopathy (moderate or greater mitral insufficiency and/or mild or greater aortic insufficiency) were similar between treatment groups.

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% (p=0.88), 2.7% vs. 2.3% (p=0.70), 2.9% vs. 3.1% (p=0.86) and 2.6% vs. 2.7% (p=1.00). At 18 and 24 months, rates of valvulopathy for lorcaserin patients crossing over to placebo were 3.6% and 1.9%, respectively.

In addition, similar numbers of mitral insufficiency shifts and aortic insufficiency shifts in Year 1 and Year 2 were reported for patients on lorcaserin and placebo.

The FDA previously requested that we rule out a 1.5-fold or greater risk of valvulopathy with 80% power. Assuming similar results in our final pivotal trial, 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.

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. BLOOM-DM is expected to complete enrollment around the end of June 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 New Drug Application, or NDA, for lorcaserin.

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, markers of inflammation and insulin resistance, 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 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 Obesity

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. Medical and related costs of obesity to the US are $123 billion per year according to a 2005 report by the International Diabetes Federation. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes. Diet and exercise should form the basis of healthy weight loss, but pharmaceutical treatment options for obesity are currently limited for the many patients that require additional help in achieving and maintaining medically important weight loss.

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, only one of which needs to be met for approval. 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 BLOOM results; the development, advancement, therapeutic indication, tolerability, safety, selectivity, efficacy and potential of lorcaserin; the FDA s guidance, process and requirements; the potential of the lorcaserin Phase 3 program and its results to meet the FDA s approval requirements, including with regard to assessing the risk of developing valvulopathy; the approval of lorcaserin for marketing; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; future activities, results and announcements relating to lorcaserin, including the submission of the BLOOM-DM results as a supplement to the lorcaserin NDA; the potential of lorcaserin in managing weight, improving health and generating patient interest; the impact of weight loss on health; lorcaserin s patent coverage; and our strategy 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 our other research and development programs; 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 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: June 8, 2009

Arena Pharmaceuticals, Inc.

By: /s/ Jack Lief
Jack Lief
President and Chief Executive Officer