ARENA PHARMACEUTICALS INC
Form 8-K
September 18, 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): September 17, 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 September 17, 2009 we announced positive, highly significant top-line results from the BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) trial. BLOSSOM confirms the results previously reported for the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial and completes the lorcaserin Phase 3 pivotal registration program of 7,190 patients evaluated for up to two years. We plan to submit a New Drug Application, or NDA, for lorcaserin to the US Food and Drug Administration, or FDA, in December.

In the one-year BLOSSOM trial, lorcaserin met all primary efficacy and safety endpoints. Patients achieved highly significant categorical and absolute weight loss. Lorcaserin was very well tolerated and was not associated with depression or suicidal ideation. The integrated echocardiographic data set from BLOSSOM and BLOOM rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Treatment with lorcaserin also resulted in significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk.

Efficacy

Per Protocol Results

Lorcaserin was highly effective in helping patients achieve significant weight loss using multiple measurements. Patients treated with 10 mg of lorcaserin dosed twice daily (BID) who completed the 52-week trial according to protocol demonstrated the benefit of long-term treatment with lorcaserin:

- 63.2% of patients lost at least 5% of their body weight ($p<0.0001$);
- 35.1% of patients lost at least 10% of their body weight ($p<0.0001$);
- Patients lost an average of 17.0 pounds, or 7.9% of their body weight; and
- The quartile of lorcaserin patients with the greatest weight loss (among those with a Week 52 weight recorded) lost an average of 35.1 pounds, or 16.3% of their body weight.

Of the placebo patients who completed the trial, 34.9% and 16.1% achieved at least 5% and 10% weight loss, respectively, and the average weight loss was 8.7 pounds, or 3.9%. The top quartile of lorcaserin patients lost 36% more body weight than the top quartile of placebo patients.

For the patients treated with 10 mg of lorcaserin dosed once daily (QD) and completing the 52-week trial according to protocol, 53.1% lost at least 5% of their body weight and 26.3% lost at least 10% of their body weight. The average weight loss in the lorcaserin 10 mg once daily group was 14.3 pounds, or 6.5%. As with the higher dose, all results were highly statistically significant ($p<0.0001$ compared to placebo).

Intent-to-Treat Last Observation Carried Forward (ITT-LOCF) Results

Measurements of efficacy using ITT-LOCF analysis also showed that lorcaserin met all primary endpoints. This analysis includes all patients who were randomized and returned for at least one weight measurement. Patients treated with 10 mg of lorcaserin once or twice daily achieved highly statistically significant categorical and average weight loss after 12 months:

Lorcaserin 10 mg Twice Daily

- 47.2% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 5% of their body weight compared to 25.0% for placebo (p<0.0001). This result satisfies the efficacy benchmark in the most recent FDA draft guidance which provides that a weight-management product can be considered effective if 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;

- 22.6% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 10% of their body weight compared to 9.7% for placebo (p<0.0001);

Lorcaserin 10 mg Once Daily

- 40.2% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 5% of their body weight (p<0.0001); and

- 17.4% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 10% of their body weight (p<0.0001).

Patients who took lorcaserin 10 mg twice daily achieved an average weight loss of 5.9% of their body weight, compared to 2.8% for placebo (p<0.0001). Similarly, patients who took lorcaserin 10 mg once daily achieved an average weight loss of 4.8% of their body weight (p<0.0001).

BLOSSOM Confirms BLOOM

In BLOSSOM, as in BLOOM, lorcaserin s excellent tolerability allowed patients to begin treatment at the full dose immediately, without a titration period, and achieve rapid weight loss. As in BLOOM, significant weight loss compared to placebo was shown at the first trial visit, two weeks following randomization.

The efficacy for the BLOOM and BLOSSOM trials after one year of treatment are summarized in the table below.

	BLOOM		BLOSSOM		
	10 mg BID*	**Placebo**	**10 mg BID***	**10 mg QD***	**Placebo**
≥5% weight loss (Per protocol)	66.4%	32.1%	63.2%	53.1%	34.9%
≥5% weight loss (ITT-LOCF)	47.5%	20.3%	47.2%	40.2%	25.0%
≥10% weight loss (Per protocol)	36.2%	13.6%	35.1%	26.3%	16.1%
≥10% weight loss (ITT-LOCF)	22.6%	7.7%	22.6%	17.4%	9.7%
Mean weight loss (Per protocol)	8.2%	3.4%	7.9%	6.5%	3.9%
Mean weight loss (ITT-LOCF)	5.8%	2.2%	5.9%	4.8%	2.8%

* p<0.0001 compared to placebo

Safety and Tolerability Profile

Lorcaserin was very well tolerated. No adverse event rate in the lorcaserin group exceeded the placebo group by more than 4%. The most frequent adverse events and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: upper respiratory infection (12.7%, 14.5%, 12.6%); nasopharyngitis (12.5%, 11.7%, 11.8%) and headache (10.0%, 10.5%, 7.6%).

Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group. Serious adverse events, or SAEs, occurred infrequently: one death occurred in the placebo group, no SAEs of seizure were reported and the number of neuropsychiatric SAEs in lorcaserin patients did not exceed the number in the placebo group.

Cardiovascular Safety

The integrated BLOOM and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Echocardiographic evaluations showed no association between lorcaserin and the development of heart valve insufficiency. Rates of new FDA-defined valvulopathy in BLOSSOM at Week 52 were as follows: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%).

Secondary Endpoints

Treatment with lorcaserin over one year was associated with significant improvements or strongly favorable trends compared to placebo in multiple secondary endpoints, including blood pressure and lipids.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average body mass index, or BMI, of 35.9 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuations for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

BLOSSOM Trial Design

BLOSSOM is a double-blind, randomized, placebo-controlled trial that enrolled 4,008 patients in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients (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 dose titration or a run-in period. Patients were randomized at baseline in a 2:2:1 ratio to lorcaserin

10 mg twice daily, placebo or lorcaserin 10 mg once daily. Patients received echocardiograms at baseline, month 6 and at the end of the trial to assess heart valve function over time. In contrast to the BLOOM trial, there were no echocardiographic exclusion criteria for entry into BLOSSOM and there was no oversight or interim data review monitoring by an independent safety monitoring board.

Phase 3 Program Overview

The lorcaserin Phase 3 program consists of three trials: BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus). Enrollment in the lorcaserin Phase 3 program is complete with approximately 7,800 patients. Positive results from BLOOM were presented at the 69th Scientific Sessions of the American Diabetes Association in June 2009. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program and will be the basis for the lorcaserin NDA submission. BLOOM-DM, which is planned as a supplement to the NDA, 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.

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.

About the FDA Draft Guidance

The FDA draft guidance document 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.

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 expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. 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 Weight Management

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. A 2009 publication in *Health Affairs* estimated the annual medical burden of obesity in the US to be $147 billion in 2008. 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 in patients with glucose intolerance.

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 significance of the BLOSSOM and BLOOM results and the completion of the lorcaserin Phase 3 pivotal registration program; the development, advancement, therapeutic indication, tolerability, safety, selectivity, efficacy and potential of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the FDA s guidance, process and requirements; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA s approval requirements, including with regard to efficacy and safety; the risk of developing valvulopathy; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin and submitting the BLOOM-DM results as a supplement to the NDA; the impact of weight loss on health; and lorcaserin s patent coverage. 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 timing, success and cost of our lorcaserin program and other of our research and development programs; results of clinical trials or preclinical studies may not be predictive of future results and top-line results are preliminary; clinical trials and studies may not proceed at the time or in the manner we expect or at all; our ability to partner or commercialize lorcaserin or other of our compounds or programs; the timing and our ability to receive regulatory approval for our drug candidates; our ability to obtain additional funds; 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.

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: September 18, 2009

Arena Pharmaceuticals, Inc.

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