ARENA PHARMACEUTICALS INC
Form 8-K
October 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): October 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)

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.

We are filing this Current Report on Form 8-K to update our filings with the Securities and Exchange Commission with information we announced at Obesity 2009, the 27th Annual Scientific Meeting of The Obesity Society.

Additional BLOOM Data

We announced at Obesity 2009 that data from the pivotal BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) Phase 3 trial demonstrate lorcaserin significantly increased excess weight loss, improved markers of cardiovascular risk and glycemic parameters, and was not associated with depression or suicidal ideation. Additional subgroup analyses showed that lorcaserin caused the greatest improvements in lipid profiles, glycemic parameters and other markers of cardiovascular risk in patients in the highest risk categories.

The new data show that lorcaserin increased excess weight loss during Year 1 of the BLOOM trial. Lorcaserin patients who completed the trial according to protocol lost 31% of their excess weight compared to 12% for the placebo group. This measurement is based on a normal Body Mass Index, or BMI, of 25. In addition to the previously announced improvements in glycemic parameters, including fasting glucose, fasting insulin and HOMA-IR, lorcaserin patients also achieved highly significant improvements in HbA1C over one year of treatment ($p<0.0001$). The greatest improvements were observed in patients with abnormal baseline values.

Quality of Life, as assessed by the Impact of Weight on Quality of Life-Lite, or IWQOL-Lite, questionnaire, also improved to a significantly greater extent in the lorcaserin group than the placebo group at Week 52 ($p<0.005$). Lorcaserin patients achieved improvements over placebo in all subscores of the IWQOL-Lite, including physical function, self esteem, sexual life, public distress and work.

In addition to the previously announced tolerability data, we also announced at Obesity 2009 that lorcaserin demonstrated no increase in depression or suicidal ideation compared to placebo. Depression and suicidal ideation were monitored prospectively using the Beck Depression Inventory-II, or BDI-II, and by adverse event reporting. At Week 52, 18.0% of lorcaserin patients and 16.1% of placebo patients reported at least a five-point improvement from baseline in BDI-II. A smaller number of lorcaserin patients had increases in the BDI-II total score as compared to placebo. Adverse events related to depression and their total rates at Year 1 for patients who took lorcaserin or placebo, respectively, were 3.1% and 3.0%. In addition, cumulative incidence of suicidal ideation was prospectively evaluated by administration of the BDI-II Questionnaire and did not differ between the lorcaserin and placebo groups at each measurement through two years of treatment.

Previously announced BLOOM data demonstrate that lorcaserin helped patients achieve clinically meaningful weight loss and maintenance of weight loss over two years of treatment. 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, and over one-third (36.2%) of lorcaserin patients lost at least 10% of their weight, compared to 13.6% for placebo. The average weight loss in this population was 17.9 pounds in the lorcaserin group, compared to 7.4 pounds in the placebo group. Using Intent-to-Treat Last Observation Carried Forward, or ITT-LOCF, analysis, 67.9% of Year 1 lorcaserin responders maintained at least 5% weight loss during Year 2, compared to 50.3% for those patients re-randomized from lorcaserin treatment in Year 1 to placebo in Year 2.

Lorcaserin improved patients lipid profiles, insulin resistance and markers of inflammation, with the greatest improvements observed in those with abnormal values at the start of the study. Treatment with lorcaserin was well tolerated, resulting in very few adverse events with greater frequency than the placebo group, and did not increase cardiac valvulopathy. Lorcaserin s tolerability profile eliminates the need for titration; patients began treatment on the full dose and achieved rapid weight loss. Almost one-third of lorcaserin patients lost at least 5% of their body weight by Week 8.

Additional BLOSSOM Data

We also announced at Obesity 2009 that data from the pivotal BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) Phase 3 trial demonstrate improvements in patients body composition, cardiovascular risk factors and quality of life. These findings add to the previously announced top-line BLOSSOM data that showed highly significant weight loss with lorcaserin over one year of treatment in 4,008 patients.

The new data demonstrate that treatment with lorcaserin over one year was associated with highly significant improvements or favorable trends compared to placebo in multiple secondary endpoints evaluated in the trial:

Body Composition

Using ITT-LOCF analysis, lorcaserin patients achieved highly significant improvements in BMI, waist circumference and hip circumference. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: BMI (kg/m squared), (-2.1, -1.7, -1.0); waist circumference (cm), (-6.2, -5.6, -4.2); and hip circumference (cm), (-5.3, -5.0, -3.3), ($p<0.0001$) compared to placebo for all measurements. In addition, lorcaserin patients lost significantly more body fat than the placebo patients.

Cardiovascular Risk Factors

Using ITT-LOCF analysis, lorcaserin helped improve patients cardiovascular risk factors. Patients dosed with 10 mg of lorcaserin once or twice daily achieved statistical significance ($p<0.05$) versus placebo at Week 52 for percent change in HDL cholesterol and triglycerides and achieved favorable trends in total cholesterol and LDL cholesterol. Lorcaserin did not increase blood pressure or heart rate at any time point. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: diastolic blood pressure (mmHg), (-1.9, -1.0, -1.5); systolic blood pressure (mmHg), (-2.0, -1.1, -1.2); and heart rate (bpm), (-2.3, -1.1, -1.6).

Quality of Life

Lorcaserin did not increase depression or suicidal ideation compared to placebo. Adverse events related to depression and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: depression (1.9%, 1.1%, 1.8%); depressed mood (0.6%, 0.9%, 0.9%); and depressive symptoms (<0.1%, 0%, 0%).

Quality of Life, as assessed by the IWQOL-Lite questionnaire, improved to a significantly greater extent in the lorcaserin twice daily ($p<0.0001$) and lorcaserin once daily ($p<0.01$) groups as compared to placebo at Week 52. All measurements, including physical function, self esteem, sexual life, public distress and work, improved in a dose-dependent fashion.

Safety and Tolerability Profile

Lorcaserin was very well tolerated. Adverse events that exceeded placebo by greater than 3% and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: headache (15.6%, 15.6%, 9.2%); nausea (9.1%, 7.6%, 5.3%); dizziness (8.7%, 6.2%, 3.9%); fatigue (8.4%, 6.6%, 4.1%); and dry mouth (5.4%, 3.4%, 2.3%). Serious adverse events occurred infrequently and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: 3.1%, 3.4% and 2.2%.

Cardiovascular Safety

The assessment of echocardiograms performed at baseline and after patients completed 6 and 12 months of dosing indicated that lorcaserin did not increase echocardiographic heart valve regurgitation. Lorcaserin met the primary safety endpoint that evaluated the rates of new FDA-defined valvulopathy in BLOSSOM at Week 52: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%). The integrated BLOOM and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA.

New data demonstrate that similar numbers of mitral insufficiency and aortic insufficiency shifts were reported for patients on lorcaserin and placebo. In patients with pre-existing FDA-defined valvulopathy at baseline, changes in valvular regurgitant scores did not differ between the placebo and lorcaserin groups. The majority of patients experienced either no change or an improvement in valvular regurgitation.

Previously Announced Efficacy Data

The previously announced BLOSSOM data demonstrated that lorcaserin was highly efficacious, achieving statistical significance on all three co-primary efficacy endpoints, and was very well tolerated. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who completed the trial according to the protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds.

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, advancement, therapeutic indication and use, tolerability, safety, selectivity, and efficacy of lorcaserin; the elimination of the need for titration; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the risk of developing valvulopathy; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA s approval requirements; and our 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, the timing, success and cost of our lorcaserin program and other of our research and development programs; regulatory authorities may not find data from our clinical trials and studies sufficient for regulatory approval; the timing and ability of us to receive regulatory approval for our drug candidates; 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 or commercialize lorcaserin or other of our compounds or programs; 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: October 30, 2009

Arena Pharmaceuticals, Inc.

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