

ARENA PHARMACEUTICALS INC

Form 8-K

June 28, 2010

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 26, 2010

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-31161
(Commission

File Number)

23-2908305
(I.R.S. Employer

Identification No.)

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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., unless the context otherwise provides.

Item 8.01 Other Events.

On June 26, 2010, we reported pooled Week 52 data from more than 6,000 patients in lorcaserin's pivotal Phase 3 clinical trial program that demonstrate lorcaserin 10 mg dosed twice daily reduced body weight in all patient subgroups evaluated, as defined by gender, age, ethnicity and starting body weight and Body Mass Index, or BMI. Greater improvements in cardiovascular risk factors were also achieved with lorcaserin treatment compared to placebo overall and in most subgroups.

The pooled data show that more than twice as many lorcaserin patients (47.1%) achieved at least 5% body weight loss compared to placebo (22.6%) using Intent-to-Treat with Last Observation Carried Forward analysis. Patients in both the lorcaserin and placebo groups who decreased their body weight by at least 5% achieved more favorable changes in lipid parameters, glycemic parameters, blood pressure and high sensitivity C-reactive protein as compared to those who had less than 5% weight loss. Greater improvements in these cardiovascular risk factors were also achieved by patients who entered the studies with values indicative of elevated risk.

The data show that patients who took lorcaserin achieved greater reductions in body weight than the placebo group in all subgroups evaluated. Lorcaserin patients achieved greater improvements in total cholesterol, triglycerides, HDL cholesterol and insulin resistance compared to placebo across all subgroups. Greater improvements were also seen in fasting insulin, fasting glucose and blood pressure for lorcaserin patients compared to placebo overall and in most subgroups. Blood pressure did not increase in any evaluated subgroup.

Phase 3 Program Overview

The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin was well tolerated and produced statistically significant weight loss. These double-blind, randomized, placebo-controlled trials evaluated obese patients, BMI 30 to 45, with or without co-morbid conditions and overweight patients, BMI 27 to 29.9, with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance.

In addition to the pivotal program, we are evaluating lorcaserin for weight management in obese and overweight patients with type 2 diabetes in our BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. Results of BLOOM-DM are expected late this year, and we plan to file the results as a supplement to the New Drug Application, or NDA.

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 advancement, therapeutic indication and use, safety, efficacy, tolerability, regulatory review and

potential of lorcaserin; and the BLOOM-DM trial, including the results of such trial. 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, regulatory authorities or advisors may not find data from our clinical trials and other studies sufficient for regulatory approval; the timing and our ability to receive regulatory approval for our drug candidates; the timing, success and cost of our lorcaserin program and other 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 we or others expect or at all; our ability to enter into agreements to develop or commercialize our compounds or programs; our ability to commercialize lorcaserin with a pharmaceutical company or independently; our ability to obtain adequate 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 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 28, 2010

Arena Pharmaceuticals, Inc.

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