ARENA PHARMACEUTICALS INC
Form 8-K
March 17, 2008

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 17, 2008**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 17, 2008, we announced that following a planned review by an independent Echocardiographic Data Safety Monitoring Board, or EDSMB, we are continuing BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), a pivotal trial evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. The EDSMB s review of unblinded echocardiographic data performed after patients completed 12 months of dosing in the trial confirmed that differences, if any, in the rates of valvulopathy, as defined by the Food and Drug Administration, or FDA, in patients treated with lorcaserin and in the control group did not meet the EDSMB s predetermined stopping criteria. Based on the EDSMB s review of the rate of FDA-defined valvulopathy, we have been able to confirm that the statistical power calculations used in the design of the Phase 3 trial program to monitor patients for increased risk of developing valvulopathy are justified. The findings from the month-12 review build on the EDSMB s September 2007 review that evaluated echocardiograms after 6 months of dosing.

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving nearly 3,200 patients in approximately 100 centers throughout the United States. The trial is evaluating a 20 mg daily dose (10 mg dosed twice daily) of lorcaserin 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 proportion of patients with a 5% or greater weight reduction from baseline at week 52 is the primary efficacy endpoint. Patients received echocardiograms at screening, 6 months and 12 months after initiating dosing in the trial, and will receive follow-up echocardiograms at 18 and 24 months. There are no further planned EDSMB meetings.

The BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin 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 United States.

The BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 45 sites in the United States.

As in the BLOOM trial, diet and exercise are also included in the BLOSSOM and BLOOM-DM trials, and the primary efficacy endpoint is the proportion of patients with a 5% or greater weight reduction from baseline at week 52. We are also studying several key secondary endpoints, including changes in serum lipids and HbA1c and, in the BLOOM-DM trial, other indicators of glycemic control.

In both of these additional trials, 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 and there is no monitoring by an independent monitoring board.

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 review of echocardiographic data; the continuation of the Phase 3 program and development of lorcaserin; the protocol, design, scope, enrollment, number, timing and other aspects of clinical trials and other studies of lorcaserin; the tolerability, side effects, safety profile, efficacy and the commercial and other potential of lorcaserin; and other statements about our outlook, 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, clinical trials and studies may not proceed at the time or in the manner we expect or at all, the results of clinical trials or preclinical studies may not be predictive of future results, our ability to partner lorcaserin, APD125, APD791 or other of our compounds or programs, the timing, success and cost of our research, out-licensing endeavors and clinical trials, our ability to obtain additional financing, our ability to obtain and defend our patents, the timing and receipt of payments and fees, if any, from our collaborators, and our ability to redeem with common stock any outstanding shares of our series B convertible preferred stock. 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: March 17, 2008

Arena Pharmaceuticals, Inc.

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