ARENA PHARMACEUTICALS INC
Form 8-K
September 11, 2007

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 11, 2007**

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/or one or more of our wholly owned subsidiaries, unless the context otherwise provides.

Item 8.01 Other Events.

On September 11, 2007, we announced that an independent Echocardiographic Data Safety Monitoring Board (the Board or EDSMB) found no reason to stop our ongoing pivotal Phase 3 trial, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management). The BLOOM trial is evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. The findings of the Board were based on a planned detailed review of unblinded echocardiograms performed after patients completed six months of dosing in the trial. The review was conducted by the Board and confirms that differences, if any, in the rates of U.S. Food and Drug Administration (FDA)-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet predetermined stopping criteria. The review also confirmed that the rate of FDA-defined valvulopathy in the placebo group is consistent with our statistical powering assumptions used in the design of the pivotal trial program to monitor patients for any increased risk of developing valvulopathy. We are currently in discussions with the FDA to finalize protocols for two additional Phase 3 pivotal trials scheduled to begin later this year. In addition, we expect the month 12 EDSMB review in the first quarter of 2008.

BLOOM is a double-blind, randomized, placebo-controlled trial involving nearly 3,200 patients in approximately 100 centers in 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 (BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to 30) with at least one co-morbid condition. The primary efficacy endpoint is the proportion of patients with a 5% or greater weight reduction from baseline at week 52 as compared to placebo. Patients received echocardiograms at screening and 6 months after initiating dosing in the trial, and will receive follow-up echocardiograms at 12, 18 and 24 months. As with the month 6 echocardiogram analysis, the EDSMB will review the month 12 echocardiographic data and, based upon predetermined criteria, will make a judgment as to whether it is appropriate to continue or stop the trial.

The complete lorcaserin program includes two Phase 3 pivotal trials in addition to BLOOM that are scheduled to start later this year. Under the protocols being finalized with the FDA, the two additional pivotal trials are expected to evaluate daily doses of 20 mg and 10 mg versus placebo over a one-year treatment period, with one of the trials evaluating patients with type 2 diabetes. Diet and exercise will be part of each of the pivotal trials in accordance with FDA guidance. Also, we have proposed to the FDA to continue conducting patient echocardiograms in these additional pivotal studies.

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 continuation of the Phase 3 BLOOM trial and development of lorcaserin, the significance of the review of echocardiographic data, the timing of the EDSMB s month 12 review of echocardiographic data, the rate of valvulopathy in the BLOOM placebo group, the timing,

number, protocol, design, scope and other aspects of lorcaserin trials, the tolerability, side effects, efficacy and potential of lorcaserin, and about 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, our planned clinical trials may not proceed at the time we expect or at all, the results of preclinical studies or clinical trials 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, 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: September 11, 2007

Arena Pharmaceuticals, Inc.

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