ARENA PHARMACEUTICALS INC
Form 8-K
December 13, 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): **December 13, 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 its wholly owned subsidiaries, unless t context otherwise provides.

Item 8.01 Other Events.

On December 13, 2007, we announced the initiation of patient screening in the second and third Phase 3 pivotal trials evaluating the efficacy and safety of our lead drug candidate, lorcaserin hydrochloride, for weight management in overweight and obese patients. Known as **BLOSSOM** (**B**ehavioral modification and **L**orcaserin **S**econd **S**tudy for **O**besity **M**anagement) and **BLOOM-DM** (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity **M**anagement in **D**iabetes **M**ellitus), these one-year, double-blind, randomized and placebo-controlled trials are expected to collectively enroll approximately 3,750 overweight and obese patients. Consistent with our proposal, the Food and Drug Administration, or FDA, is allowing patients with FDA-defined valvulopathy to enroll in both BLOSSOM and BLOOM-DM. This is different from the design of the initial lorcaserin pivotal study known as BLOOM, in which echocardiography was used to screen for patients with FDA-defined valvulopathy and exclude those patients from enrolling in the trial. Instead, in BLOSSOM and BLOOM-DM, there are no such echocardiographically defined exclusion criteria, although serial echocardiograms will be obtained to extend the lorcaserin safety database. BLOOM, BLOSSOM and BLOOM-DM comprise the entire planned pivotal trial program for lorcaserin.

The BLOSSOM trial will evaluate 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 (Body Mass Index, or 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 at about 100 sites in the United States. The BLOOM-DM trial will evaluate 10 mg and 20 mg daily doses of lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes mellitus at about 45 sites in the United States.

Consistent with the BLOOM trial, diet and exercise will also be included in the BLOSSOM and BLOOM-DM trials in accordance with current FDA guidelines, and the proportion of patients with a 5% or greater weight reduction from baseline at week 52 will be the primary efficacy endpoint. Secondary endpoints include changes in serum lipids and HbA1c and, in the BLOOM-DM trial, other indicators of glycemic control will also be evaluated. In both of these additional studies, 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 ongoing BLOOM trial, however, there will be no independent monitoring by an Echocardiographic Safety Monitoring Board. The complete lorcaserin Phase 3 pivotal program is planned to enroll a total of approximately 7,000 patients in these three trials. In addition to the planned pivotal trial program, several additional small studies, such as drug interaction and abuse potential studies, will be conducted.

We also announced that we expect that the BLOOM Echocardiographic Safety Monitoring Board s review of echocardiograms for patients completing 12 months of treatment will occur in March 2008.

We also updated an earlier estimate of the total external clinical costs of the Phase 3 trial program from approximately $125 million to approximately $160 million. The increased estimate is primarily due to the increased number of patients we plan to enroll, and to our initiative to expand the echocardiographic monitoring program by including patients with FDA-defined valvulopathy in the BLOSSOM and BLOOM-DM trials.

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 program and development of lorcaserin, the timing of the Echocardiographic Safety Monitoring Board s month 12 review of echocardiographic data, the number of patients in the Phase 3 lorcaserin clinical trials, the timing, number, protocol, design, scope, cost and other aspects of the lorcaserin trials and studies, the tolerability, side effects, efficacy and potential of lorcaserin and our strategy. 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 and studies may not proceed at the time or in the manner 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: December 13, 2007

Arena Pharmaceuticals, Inc.

By: /s/ Jack Lief
Jack Lief
President and Chief Executive Officer