ARENA PHARMACEUTICALS INC
Form 8-K
February 07, 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): **February 5, 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 our wholly owned subsidiary, BRL Screening, Inc., unless the context otherwise provides.

Item 8.01 Other Events.

On February 5, 2007, we announced that we completed patient enrollment in the first of three planned Phase 3 pivotal trials evaluating the efficacy and safety of our lead drug candidate, lorcaserin hydrochloride, for the treatment of obesity. Known as BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), this double-blinded, randomized, and placebo-controlled trial enrolled 3,182 patients at approximately 100 centers in the United States. We continue to expect BLOOM s independent Data Safety Monitoring Board (DSMB) to perform its month-six review of echocardiograms in the third quarter of 2007 and make a judgment as to whether it is appropriate to continue the trial.

The BLOOM 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 proportion of patients with a 5% or greater weight reduction from baseline at week 52 is the primary efficacy endpoint. All patients received echocardiograms at screening and will receive follow-up echocardiograms at 6, 12, 18 and 24 months after starting the trial. Echocardiograms will be reviewed by an independent DSMB at 6 and 12 months. The DSMB will review echocardiographic data, and based upon predetermined criteria will make a judgment as to whether it is appropriate to continue the trial at the time of each review.

The complete lorcaserin Phase 3 program is designed to enroll a total of approximately 6,000 overweight and obese patients in three pivotal trials. In addition to the BLOOM trial, we expect to initiate later this year two additional Phase 3 pivotal trials enrolling a total of approximately 3,000 patients. In these additional pivotal trials we plan to evaluate the 20 mg and 10 mg daily doses versus placebo over a one-year treatment period, with one of the trials likely evaluating patients who also have type 2 diabetes. Diet and exercise will be part of each of the pivotal trials in accordance with the FDA guideline. In addition to the above planned pivotal trial program, several other small studies, such as drug interaction and abuse potential studies, will be conducted.

About Lorcaserin

Lorcaserin, our orally administered, internally discovered drug candidate for the treatment of obesity, is in an ongoing Phase 3 program. The compound stimulates the 5-HT2C serotonin receptor, located in the hypothalamus, an area of the brain which helps regulate satiety and influences metabolic rate. Results from a Phase 2 study demonstrated that treatment with lorcaserin produced highly statistically significant, progressive and dose-dependent weight loss over a 12-week period. In the study, which excluded diet and exercise, patients taking a daily 20 mg dose of lorcaserin realized a mean weight loss of 7.9 pounds, while patients on placebo lost less than one pound. Lorcaserin was generally well tolerated at all doses and had no apparent effects on heart valves or pulmonary artery pressure.

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 timing, protocol, design, scope and other aspects of the current and planned Phase 3 clinical trials and other studies of lorcaserin, the potential efficacy and tolerability of lorcaserin, the expected role and acts of the DSMB, the timing of DSMB reviews and other statements about our 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, 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 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: February 7, 2007

Arena Pharmaceuticals, Inc.

By: /s/ Steven W. Spector
Steven W. Spector
SVP, General Counsel and Secretary