ARENA PHARMACEUTICALS INC
Form 8-K
June 13, 2006

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 12, 2006**

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 CFR240.13e-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 June 12, 2006, Steven Smith, M.D., principal investigator in the study and associate professor and chief, in-patient unit of the Pennington Biomedical Research Center presented data from Arena s Phase 2b clinical trial of lorcaserin hydrochloride (formerly APD356) for the treatment of obesity in an oral presentation at the 66th Annual Scientific Sessions of the American Diabetes Association (ADA) in Washington, DC. When compared to placebo, patients treated with lorcaserin experienced a highly statistically significant average weight loss and reductions in other physical measures, including body mass index (BMI) and waist and hip circumference. Trends or improvements were seen in fasting glucose and most lipid measures despite normal mean baseline values and the relatively short study duration. We are currently in discussions with the FDA about initiating a Phase 3 trial of lorcaserin in obese patients later this year.

Lorcaserin Phase 2b Study Results

Patients completing the twelve week treatment period with lorcaserin achieved a highly statistically significant ($p<0.001$) mean weight loss of 4.0, 5.7 and 7.9 pounds at daily doses of 10 mg, 15 mg and 20 mg (10 mg dosed twice daily), respectively, compared to 0.7 pounds for the placebo group. Using an intent-to-treat, last-observation-carried-forward (ITT-LOCF) analysis, treatment with lorcaserin was also associated with a highly statistically significant ($p<0.001$) average weight loss of 3.7, 4.8 and 6.8 pounds at daily doses of 10 mg, 15 mg and 20 mg, respectively, in patients taking lorcaserin compared to 0.4 pounds for the placebo group.

The proportions of patients completing the twelve week treatment period with lorcaserin who achieved a 5% or greater weight loss from baseline were 13% ($p=0.015$), 20% ($p<0.001$) and 31% ($p<0.001$) at daily doses of 10 mg, 15 mg and 20 mg, respectively, compared to 2% in the placebo group. As in the prior Phase 2a clinical trial, weight loss was progressive.

Treatment with lorcaserin was also associated with dose-dependent and statistically significant improvements in BMI ($p<0.001$ for all three doses), waist circumference ($p=0.017$ for the 15 mg dose; $p=0.001$ for the 20 mg dose), hip circumference ($p=0.017$ for the 20 mg dose), cholesterol ($p=0.019$ for the 15 mg dose; $p=0.006$ (-3.7%) for the 20 mg dose), and fasting blood sugar ($p=0.028$ (-3.0%) for the 20 mg dose). Positive, dose-dependent trends on LDL-cholesterol and triglycerides were also observed, and there was no apparent effect on blood pressure.

A small, non-dose dependent decrease of 3.3-3.5% was observed in HDL levels that was marginally statistically significant at all doses ($p=0.038$-0.053). The decrease in HDL levels resulted in slight increases in LDL:HDL ratios, which were also non-dose dependent and not statistically significant. A similar small increase was also observed in the placebo group.

Lorcaserin was generally well tolerated at all doses investigated in the trial. Adverse events occurring in greater than 5% in any of the dosed groups were headache, nausea, dizziness, vomiting, dry mouth, nasopharyngitis, fatigue and urinary tract infection.

An assessment of baseline and Day 85 echocardiograms indicated no apparent lorcaserin effect on heart valves or pulmonary artery pressure. No changes in valvular regurgitation greater than one category, no significant differences between any treatment group and placebo in number of increases in valve regurgitation at any valve, and no significant increases in pulmonary artery pressure in any group were identified in the echocardiogram results.

Lorcaserin Phase 2b Study Design

The Phase 2b clinical trial was a randomized, double-blinded, dose-ranging study conducted at approximately 40 sites in the United States. The trial enrolled 469 male and female obese patients with a BMI of between 29 and 46. Patients were randomized into four groups to evaluate the safety and efficacy of daily 10 mg, 15 mg and 20 mg (10 mg dosed twice daily) doses of lorcaserin compared to placebo for 12 weeks. The primary efficacy endpoint of the Phase 2b study was a reduction in weight in patients completing the 12 week treatment period. In addition to standard safety evaluations, patients were assessed by echocardiogram prior to enrollment and at the end of the treatment period. Patients did not receive any diet or exercise advice, but were required to abstain from consuming alcohol during the study.

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 the statements about the clinical trials and results of lorcaserin hydrochloride and other statements about our strategy, technologies, preclinical and internal and partnered clinical programs, 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, the FDA may not allow our planned clinical trials to 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 hydrochloride, 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: June 12, 2006

Arena Pharmaceuticals, Inc.,
a Delaware corporation

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