ARENA PHARMACEUTICALS INC
Form 8-K
December 13, 2005

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, 2005**

Arena Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in 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))

Item 8.01. Other Events.

On December 13, 2005, Arena Pharmaceuticals, Inc. announced top-line results from its Phase 2b clinical trial of APD356, Arena s orally administered, internally discovered drug candidate for the treatment of obesity. Over the 12 week treatment period, there was a statistically significant ($p<0.001$) average 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, in patients taking APD356 compared to 0.7 pounds for the placebo group. APD356 was generally well tolerated at all doses investigated in the trial and there were no apparent effects on heart valves or pulmonary artery pressures. APD356 is a selective agonist of 5-HT2C serotonin receptors, which are located in the hypothalamus, an area of the brain that plays an important role in regulating food intake and metabolism.

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 body mass index (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 before breakfast and 10 mg before dinner) doses of APD356 compared to placebo for 12 weeks. The 20 mg dose (10 mg dosed twice daily) was designed to provide similar peak blood levels as the 15 mg once daily dose, but higher blood trough levels, thereby maintaining higher average drug concentrations in the blood. It was also designed to provide a second peak in drug level to cover the evening hours. 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.

Patient demographic characteristics at baseline were well balanced across the treatment groups. Eighty-seven percent of participants were women, 53% were Caucasian, 29% were African-American and 18% were Hispanic. At baseline, the average age was 41.5 years, the average weight was 220 pounds, and the average BMI was 36.4.

The primary efficacy endpoint of the Phase 2b study was a reduction in weight in patients completing the 12 week treatment period. Compared to placebo, treatment with APD356 was associated with a statistically significant ($p<0.001$) average weight loss of 4.0, 5.7 and 7.9 pounds at daily doses of 10 mg, 15 mg and 20 mg, respectively, in patients taking APD356 compared to 0.7 pounds for the placebo group.

Using an intent-to-treat last observation carried forward (ITT-LOCF) analysis, treatment with APD356 was also associated with a 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 APD356 compared to 0.4 pounds for the placebo group.

APD356 was generally well tolerated at all doses investigated. Four serious adverse events occurred in the trial: two in the placebo group (pneumonia and kidney stone in a single patient), one in the 10 mg group (major depression, judged unlikely study drug related due to preexisting symptoms) and one in the 20 mg group (new onset seizure, judged unlikely study

drug related by a consulting neurologist). Adverse events were generally single, self-limited events that were mild or moderate in nature.

An assessment of echocardiograms taken at baseline and at the end of the treatment period indicates no apparent APD356 effect on heart valves or pulmonary artery pressures.

Arena also announced that it is planning for the end of its Phase 2 meeting with the FDA and to move the APD356 program into Phase 3 next year.

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 results of Arena s Phase 2 clinical trial of APD356, the timing of the end of the Phase 2 meeting with the FDA regarding APD356 and the Phase 3 clinical trial of APD356, and the tolerability, side effects and efficacy of APD356. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena s expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the results of Arena s clinical trials, including that the full results of the Phase 2b clinical trial of APD356 may vary from the top-line results, the results of preclinical studies or clinical trials may not be predictive of future results, Arena s ability to partner APD356, the timing, success and cost of Arena s research, out-licensing endeavors and clinical trials, Arena s ability to obtain additional financing, Arena s ability to obtain and defend its patents, and the timing and receipt of payments and fees, if any, from Arena s collaborators, including Ortho-McNeil and Merck. Additional factors that could cause actual results to differ materially from those stated or implied by Arena s forward-looking statements are disclosed in Arena s filings with the Securities and Exchange Commission. These forward-looking statements represent Arena s judgment as of the time of the filing of this Form 8-K. Arena disclaims 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, 2005

Arena Pharmaceuticals, Inc.,
a Delaware corporation

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