ARENA PHARMACEUTICALS INC
Form 8-K
May 11, 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): **May 10, 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 May 10, 2005, Arena Pharmaceuticals, Inc. publicly announced top-line results from its Phase 2 clinical trial of APD356, Arena s orally administered, internally discovered drug candidate for the treatment of obesity. Over the 28 day treatment period, there was a highly statistically significant (p=.0002) average weight loss of 2.9 pounds in patients taking the 15 mg dose of APD356 versus 0.7 pounds for the placebo group. APD356 was generally well tolerated at all doses investigated in the trial. APD356 is a selective agonist of 5-HT2C serotonin receptors, which are located in the hypothalamus, an area of the brain known to play an important role in regulating food intake and metabolism.

This Phase 2 clinical trial of APD356 was a randomized, double-blinded, multiple-dose study examining 352 obese volunteers at 24 clinical sites in the United States. The trial was to enroll otherwise healthy male and female patients with a body mass index (BMI) of between 30 and 45. Patients were randomized into four groups to compare doses of 1, 5 and 15 mg of APD356 versus placebo. The trial evaluated safety and weight loss after oral administration of APD356 once daily for 28 days. The trial protocol provided that patients should maintain their normal diet and level of activity, but required that patients abstain from consuming alcohol. In addition to standard safety evaluations, patients were assessed by echocardiogram upon enrollment, and were scheduled for follow-up echocardiograms at 29 and 90 days after receiving their first dose.

Patient demographic characteristics at baseline were well balanced across treatment groups. Eighty percent of participants were women, 55% were Caucasian, 25% African-American and 18% Hispanic. At baseline, the average age was 40 years, the average weight was 223 pounds (range 158-468 pounds), and the average BMI was 36.

The primary efficacy endpoint of the Phase 2 study was a reduction in weight in patients completing the 28 day treatment period (Day 29). Compared to placebo, treatment with APD356 was associated with a highly statistically significant average weight loss of 2.9 pounds in the 15 mg group versus 0.7 pounds in the placebo group. No statistically significant weight loss was observed in the 1 mg or 5 mg groups. Similar results were observed in the intent-to-treat, last observation carried forward (LOCF) analysis. The table below summarizes the mean weight change for all patients completing the study in each group.

Group	Mean Weight Change from Baseline (pounds)	p value (relative to placebo)
Placebo (n=71)	-0.7	
1.0 mg (n=75)	-0.7	Not statistically significant
5.0 mg (n=72)	-0.9	Not statistically significant
15.0 mg (n=69)	-2.9	p = 0.0002

APD356 was generally well tolerated at all doses investigated, and there were no serious adverse events in the trial. Events that occurred in 5% or more of patients in a treatment group are listed below.

Event	Placebo	1 mg	5 mg	15 mg
Nausea	3.5%	5.6%	5.6%	6.9%
Nasopharyngitis	5.8%	4.4%	3.4%	1.1%
Headache	14.0%	15.6%	7.9%	20.7%
Cough	1.2%	5.6%	2.2%	1.1%

There was no apparent drug effect on the heart as assessed by Day 29 echocardiograms. Post day 29 echocardiograms are pending.

Arena intends to use these results to initiate a Phase 2b trial enrolling approximately 300 to 400 patients in a study designed to investigate the efficacy and safety of APD356 over a three-month period.

Arena Pharmaceuticals® and Arena® are registered service marks of the company.

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 APD356 s safety profile, potency and pharmaceutical behavior, expectations for future studies of APD356, and the pending echocardiograms. 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 risk that the results of clinical trials may not be predictive of future results, Arena s ability to partner APD356, the results of any future studies of APD356, the results of echocardiograms, the timing, success and cost of Arena s research, out-licensing endeavors and clinical studies, Arena s ability to obtain additional financing, 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: May 11, 2005

Arena Pharmaceuticals, Inc.,
a Delaware corporation

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