ARENA PHARMACEUTICALS INC
Form 8-K
June 30, 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): **June 30, 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 June 30, 2005, Arena Pharmaceuticals, Inc. publicly announced top-line results from its Phase 1 clinical trials of APD125, Arena s orally administered, internally discovered drug candidate for the treatment of insomnia. APD125 was well tolerated at all doses investigated. The data demonstrated a statistically significant increase in the amount of deep, or slow wave, sleep and a positive signal in other sleep maintenance parameters, which may distinguish APD125 from currently available sleep therapeutics. APD125 may have extended sleep onset latency in normal volunteers. APD125 is a novel and highly selective inverse agonist of the 5-HT2A serotonin receptor.

The Phase 1 program consisted of three clinical trials, APD125-001, APD125-002 and APD125-003, designed to evaluate the single and multiple dose safety and pharmacokinetics of APD125 in normal volunteers. Additionally, it evaluated the pharmacodynamics of nighttime dosing using polysomnography to assess effects on sleep patterns in normal volunteers.

APD125-001

The APD125-001 trial enrolled 45 healthy male volunteers in a randomized, double-blinded, placebo-controlled study evaluating the safety, tolerability and pharmacokinetics of single escalating doses of APD125 in five cohorts of nine volunteers each. Six volunteers in each cohort received one daytime dose of APD125 while three volunteers received placebo. The first cohort was administered 10 mg of APD125, which was subsequently increased to 20 mg, 40 mg, 80 mg and 160 mg in each successive cohort after safety and pharmacokinetics were evaluated in the prior cohort. In addition to safety and pharmacokinetic evaluation, this trial included waking electroencephalographic (EEG) readings taken after dosing to examine brain wave activity to help guide dose selection in the 002 trial.

Top-line results demonstrated that APD125 was well tolerated at all doses investigated. Pharmacokinetics were related to dose at the 10 mg, 20 mg and 40 mg doses, demonstrating good dose proportionality. At 40 mg, the maximum concentration in the body, or Cmax, of APD125 plateaued; there were no significant differences in Cmax among the 40 mg, 80 mg and 160 mg doses. At 80 mg, the total overall exposure, or AUC (0-inf), of APD125 also plateaued; the pharmacokinetics at the 160 mg dose were generally similar to the 80 mg dose. The maximum tolerated dose was not defined in the trial and higher doses were not tested because of the similar pharmacokinetics observed at the 80 mg and 160 mg doses. At the 40 mg dose the drug plasma half life was 10.8 hours and the mean residence time, or the average time the drug resided in the blood, was 6.8 hours.

An effect promoting delta, or slow, wave activity was observed in the waking EEGs. The effect peaked at the 40 mg dose.

The incidence of adverse events was similar to placebo.

APD125-002

The APD125-002 trial was a randomized, double-blinded, placebo-controlled study evaluating the safety, pharmacodynamics and efficacy of nighttime dosing in 24 healthy male and female volunteers, ages 45 to 65, with normal sleep/wake patterns. This trial employed a cross-over design, meaning that each volunteer randomly received each of three treatment doses (10 mg, 20 mg and 40 mg), in addition to placebo, separated by at least one week to allow for wash out of the study drug. Polysomnography was used to evaluate the effects on sleep patterns in these normal volunteers.

Top-line results demonstrated an improvement in slow wave sleep at all doses investigated. The improvement at the 40 mg dose was an increase of 60 percent, which was highly statistically significant (p=.0002). The trial also provided a positive signal on other sleep maintenance parameters. APD125 may have extended sleep onset latency by up to an average of about 12 minutes in these healthy volunteers with normal sleep/wake patterns. The apparent effect on sleep onset latency did not affect total sleep time between the APD125 and placebo groups, and it contradicts a sleep induction effect reported by volunteers in the 001 trial. This sleep onset latency effect is believed to be an anomaly, but will be studied in future trials along with other common sleep evaluation measures.

APD125 was well tolerated at all doses investigated in this trial and the incidence of adverse events was similar to placebo. Three volunteers were discontinued for adverse events, none of which appear related to APD125.

APD125-003

The APD125-003 trial enrolled 27 healthy male volunteers in a randomized, double-blinded, placebo-controlled study evaluating the safety, tolerability and pharmacokinetics of escalating daytime doses of APD125 given once daily for seven consecutive days in three cohorts of nine volunteers each. Six volunteers in each cohort received APD125, while three volunteers received placebo. The first cohort received once daily 20 mg doses of APD125 for seven consecutive days, which was subsequently increased to 40 mg and 80 mg in each successive cohort after safety and pharmacokinetics were evaluated in the prior cohort. The doses evaluated were chosen based on the results of the APD125-001 trial.

APD125 was well tolerated at all doses investigated in this trial and pharmacokinetics, dose proportionality and side effects were consistent with the findings from the 001 trial. The results indicate that APD125 given once daily over seven consecutive days was well tolerated at all doses investigated, and there were no serious adverse events.

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 APD125 s safety profile, efficacy and pharmaceutical behavior, including differences between APD125 and currently marketed drugs, APD125 s effect on sleep onset latency, and expectations

for future studies of APD125. 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 APD125, the results of any future studies of APD125, 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: June 30, 2005

Arena Pharmaceuticals, Inc.,
a Delaware corporation

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