ARENA PHARMACEUTICALS INC
Form 8-K
September 25, 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): **September 25, 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 one or more of our wholly owned subsidiaries, unless the context otherwise provides.

Item 8.01 Other Events.

On September 25, 2007, we announced preliminary results from our Phase 2 clinical trial of APD125 in patients with chronic insomnia. APD125 is an orally available drug candidate discovered by us that is being evaluated in insomnia patients who have difficulty maintaining sleep after initial sleep onset. When compared to placebo, patients treated with APD125 experienced statistically significant improvements in measurements of sleep maintenance, or the ability to maintain sleep during the night after falling asleep. The improvements in measurements of sleep maintenance were achieved without any limiting next day cognitive effects. The data from the APD125 Phase 2 study are consistent with Phase 1 data and support further development of APD125 for the treatment of insomnia patients who have difficulty maintaining sleep.

The Phase 2 trial of APD125 was a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of nighttime dosing in patients with chronic insomnia. The trial evaluated standard measurements of sleep, such as wake after sleep onset (WASO), wake time during sleep (WTDS), number of awakenings, number of arousals, total sleep time and latency to persistent sleep, and enrolled a total of 173 male and female patients in about 25 clinical sites in the United States. The trial employed a cross-over design: every patient received both active doses of APD125 (10 mg and 40 mg) and placebo in random order, for one week, separated by a seven to nine day washout period between each dosing period. Efficacy was measured objectively by averaging polysomnography values for nights one and two (N 1/2) and for nights six and seven (N 6/7), versus baseline values. Efficacy was also measured subjectively using patient-completed questionnaires each morning following polysomnography evaluations.

APD125 significantly improved several endpoints measuring improvements in sleep maintenance, including WASO and WTDS. WASO is the time spent awake from first sleep to the end of a standardly prescribed eight hour sleep period. WTDS is the cumulative time spent awake from first falling asleep and last sleep: if a patient completes his or her sleep prior to the end of the eight hour sleep period, this time spent awake in bed is not included. As such, WTDS only accounts for time awake during a patient s sleep period for that night.

WTDS decreased from baseline by 45.8 and 46.6 minutes, respectively in the 10 mg and 40 mg doses at N 1/2, and by 46.1 and 46.9 minutes, respectively, at N 6/7; these differences were statistically significant for both doses at N 1/2 ($p<0.0001$ compared to placebo decrease from baseline of 32.4 minutes) and N 6/7 ($p=0.0009$ for 10 mg, $p=0.0004$ for 40 mg compared to placebo decrease from baseline of 35.6 minutes). The decrease from baseline in WASO was 52.5 and 53.5 minutes, respectively, for the 10 mg and 40 mg doses at N 1/2 ($p<0.0001$ for both compared to placebo decrease from baseline of 37.8 minutes). Improvements from baseline in WASO of 51.7 and 48.0 minutes were observed at N 6/7 ($p=0.0131$ and $p=0.1994$ compared to placebo improvement from baseline of 44.0 minutes).

Significant improvements also were seen in other important measurements of sleep maintenance, including a decrease in the number of awakenings and arousals ($p<0.0001$ at both N 1/2 and N 6/7 at 10 mg and 40 mg for both variables). Changes in the number of awakenings were 0.0,

-2.5, and -3.1 at N 1/2 and -0.9, -2.3, and -2.5 at N 6/7 for placebo, 10 mg, and 40 mg, respectively. Changes in the number of arousals were +3.8, -5.8, and -8.1 on N 1/2 and +2.5, -4.8, and -6.7 on N 6/7 for placebo, 10 mg, and 40 mg, respectively. APD125 also significantly increased the time spent in deep (Stage 3 and 4) sleep and at the same time decreased the amount of time spent in light (Stage 1) sleep ($p<0.0001$ at 10 mg and 40 mg for both measures), providing further evidence for the sleep maintenance properties of APD125. Time in REM sleep was not meaningfully affected. As expected, based on the mechanism of APD125, no improvement in sleep onset was observed.

	WTDS (improvement in minutes from baseline)		**WASO (improvement in minutes from baseline)**		**Changes in # of Awakenings**		**Changes in # of Arousals**	
Dose	**N 1/2**	**N 6/7**	**N 1/2**	**N 6/7**	**N 1/2**	**N 6/7**	**N 1/2**	**N 6/7**
Placebo	32.4	35.6	37.8	44.0	0.0	-0.9	+3.8	+2.5
10 mg	45.8	46.1	52.5	51.7	-2.5	-2.3	-5.8	-4.8
p value	<0.0001	0.0009	<0.0001	0.0131	<0.0001	<0.0001	<0.0001	<0.0001
40 mg	46.6	46.9	53.5	48.0	-3.1	-2.5	-8.1	-6.7
p value	<0.0001	0.0004	<0.0001	0.1994	<0.0001	<0.0001	<0.0001	<0.0001

While the study was not powered to demonstrate significance in the subjective endpoints, there were trends towards improvements in the quality of sleep, number of awakenings and total sleep time, with statistical significance for at least one time point and dose for each of these variables. The improvement was numerically greater for the 40 mg dose than the 10 mg dose for many of the objective and subjective measures.

Treatment with APD125 was well tolerated, with no reports of serious adverse events and no emerging safety findings as compared to placebo. No next day impairment of cognitive function was observed.

The data from the trial indicate that APD125 is efficacious for promoting sleep maintenance in patients with chronic insomnia. Based on the positive trial results, we plan to initiate a Phase 3 program in 2008. We are also considering an additional Phase 2 study that will evaluate the effects of APD125 on patients subjective assessment of sleep.

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 the Phase 2 trial of APD125, continued development of APD125, the timing, number, protocol, design, scope and other aspects of APD125 trials, the tolerability, side effects, efficacy and the commercial and other potential of APD125, the relevance of indicators of sleep maintenance, and our 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,

APD791 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: September 25, 2007

Arena Pharmaceuticals, Inc.

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