ARENA PHARMACEUTICALS INC
Form 8-K
December 11, 2009

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 10, 2009

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:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ 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 its wholly owned subsidiaries, unless context otherwise provides.

Item 8.01 Other Events.

On December 10, 2009, we reported that positive data from a clinical trial evaluating the abuse potential of lorcaserin were presented in a poster session at the 48th Annual Meeting of the American College of Neuropsychopharmacology. Data from the trial demonstrate that the risk for abuse associated with lorcaserin is very low.

Investigational drugs that act through mechanisms in the brain are generally required to undergo an evaluation to determine abuse potential. This determination will be made by the US Drug Enforcement Administration, or DEA, with input from the US Food and Drug Administration, or FDA, as part of the regulatory review process. Lorcaserin was studied in a standard paradigm at doses well above the intended therapeutic dose of 10 mg twice daily. The clinical trial compared the relative abuse potential of lorcaserin against three comparators: placebo, zolpidem (a schedule IV controlled substance) and ketamine (a schedule III controlled substance).

The trial was a randomized, placebo-controlled, double-blind, seven-way crossover trial conducted in 35 healthy male and female recreational drug users. Subjects received single doses of lorcaserin (20 mg, 40 mg and 60 mg), zolpidem (15 mg and 30 mg), ketamine (100 mg) and placebo in a blinded fashion. Following dosing, subjects completed tests that assessed their subjective states and the drugs effects (both positive and negative). The primary endpoint was derived from the scores on a drug liking scale.

The subjects reported neutral drug liking scores for placebo and positive drug liking scores for zolpidem and ketamine, which confirmed study validity. The subjective effects of the 20 mg lorcaserin dose were similar to those of placebo. Drug liking was significantly lower for the 40 mg and 60 mg lorcaserin doses as compared to zolpidem and ketamine, and subjects demonstrated significant disliking of these supratherapeutic doses of lorcaserin compared to placebo. The subjects willingness to take lorcaserin again for recreational purposes was significantly lower for 40 mg and 60 mg doses as compared to placebo.

Data from the trial demonstrate that the risk for abuse associated with lorcaserin is very low and less than that of zolpidem or ketamine. At the supratherapeutic doses, lorcaserin was associated with distinct, primarily negative, subjective effects. Although the majority of subjects who took lorcaserin at the supratherapeutic doses in this trial reported adverse events, most often headache, only two subjects withdrew from the trial because of an adverse event.

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 risk for abuse associated with lorcaserin; the significance of abuse liability studies; the determination of a drug s abuse potential; and the development, advancement, therapeutic indication and use, tolerability, safety, selectivity and efficacy of lorcaserin. 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, regulatory authorities may

disagree with the assessment of the abuse and other study results or find data from our clinical trials and studies not sufficient for regulatory approval; the timing, success and cost of our lorcaserin program and other of our research and development programs; the timing and ability of us to receive regulatory approval for our drug candidates; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner we expect or at all; our ability to partner or commercialize lorcaserin or other of our compounds or programs; our ability to obtain additional funds; 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 other filings with the Securities and Exchange Commission. These forward-looking statements represent our judgment as of the time of the filing of this 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: December 11, 2009

Arena Pharmaceuticals, Inc.

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