ARENA PHARMACEUTICALS INC
Form 8-K
October 20, 2010

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): October 20, 2010

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, Company, we, us and our refer to Arena Pharmaceuticals, Inc., unless the context otherwise provides.

Item 8.01 Other Events.

On October 20, 2010, we announced results from a Phase 1 clinical trial of APD916, a novel drug candidate we discovered that targets the histamine H3 receptor for the treatment of narcolepsy with cataplexy.

The randomized, double-blind and placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of 1 mg, 3 mg and 5 mg single doses of APD916. The trial evaluated 24 healthy volunteers in three cohorts of eight participants each, six randomized to APD916 and two to placebo. APD916 demonstrated dose-proportional pharmacokinetic exposure over the tested dose range. The terminal half-life was approximately 50 hours.

Dose-limiting CNS adverse events occurred at the 5 mg dose, including insomnia, abnormal dreams and a nightmare. Adverse events of insomnia, nausea, headache, parosmia, alterations in perception of body temperature, abnormal dreams and visual and tactile hallucinations were commonly reported at the 3 mg and 5 mg doses, and adverse events of insomnia were commonly reported at the 1 mg dose. All adverse events in the trial were mild or moderate in nature. No serious adverse events were reported nor were there any significant safety issues with respect to vital signs, ECGs or laboratory testing.

About APD916

APD916, a potent and selective inverse agonist of the histamine H3 receptor, is our internally discovered drug candidate for the treatment of narcolepsy with cataplexy. The histamine H3 receptor is predominantly expressed in the brain, and inverse agonists of the H3 receptor increase the synthesis and release of histamine through inhibition of presynaptic autoreceptors. Enhanced histamine release plays an important role in arousal, and the histaminergic system is at least partly under the control of orexin/hypocretin neurons. Narcolepsy with and without cataplexy have been associated with orexin/hypocretin deficiency and low levels of histamine in cerebrospinal fluid. Therefore, an H3 inverse agonist, by increasing central histamine activity, may potentially be effective in the treatment of these conditions.

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 development, therapeutic indication and use, safety, efficacy, tolerability, and mechanism of action of APD916; and the potential of APD916 and H3 inverse agonists in general, including in the treatment of narcolepsy. 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, the risk that regulatory authorities may not find data from our clinical trials and other studies sufficient for regulatory approval; the timing of any regulatory review and approval is uncertain; our ability to obtain and defend our patents; risks related to commercializing new products; the timing, success and cost of our research and development programs; results of clinical trials and other studies are subject to different

interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner we or others expect or at all; our ability to obtain adequate funds; the timing and receipt of payments and fees, if any, from Eisai Inc. and our collaborators; and satisfactory resolution of pending and any future litigation or other disagreements with others. 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 report. 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: October 20, 2010

Arena Pharmaceuticals, Inc.

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