ARENA PHARMACEUTICALS INC
Form 8-K
March 24, 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): March 24, 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, we, us and our refer to Arena Pharmaceuticals, Inc., and its wholly owned subsidiaries, unless context otherwise provides.

Item 8.01 Other Events.

On March 24, 2010, we announced the initiation of patient screening in a Phase 1 clinical trial of APD916, a novel oral drug candidate we discovered that targets the histamine H3 receptor for the treatment of narcolepsy and cataplexy.

This randomized, double-blind and placebo-controlled Phase 1 trial is planned to enroll up to 72 healthy adult volunteers and will evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD916.

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 and 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, could be effective in the treatment of these conditions. APD916 was efficacious in multiple preclinical models, and the data suggest APD916 has potential utility in the treatment of narcolepsy with or without cataplexy.

About Narcolepsy and Cataplexy

Narcolepsy is a chronic neurological disorder caused by the brain s inability to regulate sleep-wake cycles normally. At various times throughout the day, people with narcolepsy experience irresistible bouts of sleep. If the urge becomes overwhelming, individuals will fall asleep for periods lasting from a few seconds to several minutes. Cataplexy, or the sudden loss of voluntary muscle tone triggered by emotional factors, is a symptom of narcolepsy and can cause a range of physical changes, from slurred speech to complete weakness of most muscles.

According to the National Institutes of Health, or NIH, narcolepsy is not rare, but it is an underrecognized and underdiagnosed condition. The NIH estimates that narcolepsy affects about one in every 2,000 Americans. Treatments are limited and consist of stimulant drugs to suppress daytime sleepiness and antidepressants for cataplexy.

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, tolerability, safety and efficacy of APD916; the potential of APD916 and H3 inverse agonists in general, including in the treatment of narcolepsy with or without cataplexy; and the protocol, design, scope, enrollment and other aspects of the Phase 1 program for APD916. 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 not find data from our clinical trials and other studies sufficient for regulatory approval; the timing and our ability to receive regulatory approval for our drug candidates; the timing, success and cost of our lorcaserin program and other 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 enter into agreements to develop or commercialize our compounds or programs; our ability to commercialize lorcaserin with a pharmaceutical company or independently; our ability to obtain adequate 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 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: March 24, 2010

Arena Pharmaceuticals, Inc.

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