ARENA PHARMACEUTICALS INC
Form 8-K
July 13, 2011

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): July 12, 2011

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 July 12, 2011, we announced results from a Phase 1 clinical trial of APD811, an orally bioavailable agonist of the prostacyclin receptor which is intended for the treatment of pulmonary arterial hypertension, or PAH.

The randomized, double-blind and placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of 0.03 mg, 0.05 mg, 0.1 mg and 0.2 mg single doses of APD811. The trial evaluated 32 healthy volunteers in four cohorts of eight participants each six randomized to APD811 and two to placebo. APD811 was rapidly absorbed and demonstrated dose-proportional pharmacokinetic exposure over the tested dose range. The terminal half-life was approximately 20 hours.

The most frequent treatment-emergent adverse events were headache, vomiting, nausea, jaw pain and flushing. Dose-limiting adverse events of nausea and vomiting occurred at the 0.2 mg dose. As compared to placebo, heart rate trended higher at the 0.05 mg, 0.1 mg and 0.2 mg doses and the corrected QT, or QTc, interval trended higher at the 0.1 mg and 0.2 mg doses. We believe the QTc observation is not supported by preclinical data and will further evaluate this in future studies. No serious adverse events were reported.

We believe the results of this early stage clinical trial suggest APD811 has the potential for once-daily, oral dosing, and our next step will be to evaluate the safety, tolerability and pharmacokinetics of multiple dosing and the optimal titration schedule in a Phase 1b trial.

About Pulmonary Arterial Hypertension, or PAH

PAH is a progressive, life-threatening disorder characterized by increased pressure in the arteries that carry blood from the heart to the lungs. The increased pressure strains the heart, which can lead to limited physical activity and a reduced life expectancy. Over time, the heart weakens, can no longer pump blood efficiently and may eventually fail.

About APD811

APD811, an orally bioavailable agonist of the prostacyclin receptor, is an investigational drug candidate discovered by us and intended for the treatment of PAH. Prostacyclin receptor agonists slow disease progression and improve exercise tolerance in PAH patients and are among the treatments administered as standard of care for advanced PAH. Currently available prostacyclin receptor agonists belong to the prostanoid class of molecules, and these products need to be administered frequently or continuously through intravenous, subcutaneous or inhaled delivery methods. We believe that an orally bioavailable, non-prostanoid prostacyclin receptor agonist that provides clinical benefits similar to currently available prostacyclin receptor agonists has the potential to improve the standard of care for PAH.

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 advancement, therapeutic indication and use, safety, efficacy, tolerability and mechanism of action of APD811; the potential of APD811 and orally bioavailable, non-prostanoid prostacyclin receptor agonists in general; future study and evaluation of APD811; and our beliefs. 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 following: there was a small safety margin from the no observed adverse effect level to significant adverse events in preclinical studies of APD811, and APD811 could have an unacceptable safety and efficacy profile in humans; the timing of regulatory review and approval is uncertain; the risk that data and other information related to our research and development programs may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; our response to the CRL for the lorcaserin NDA or submission of a Marketing Authorization Application for regulatory approval of lorcaserin may not be submitted when anticipated, if at all; the FDA may request other information prior to or after we submit such response or approval of the lorcaserin NDA; unexpected or unfavorable new data; risks related to commercializing new products; our ability to obtain and defend our patents; 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 expected or at all; our ability to obtain adequate funds; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from 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 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: July 12, 2011

Arena Pharmaceuticals, Inc.

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