ARENA PHARMACEUTICALS INC
Form 8-K
December 13, 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): December 10, 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 December 10, 2010, we announced the initiation of dosing in a Phase 1 clinical trial of APD811, a novel oral drug candidate we discovered that targets the prostacyclin receptor for the treatment of pulmonary arterial hypertension, or PAH.

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 APD811.

About 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 puts a strain on the heart, which can lead to limited physical activity and a reduced life expectancy. Over time, the heart muscle weakens and can no longer pump blood efficiently. If PAH is not treated, the heart will eventually fail. Data from the National Institutes of Health Registry indicate that without treatment, patients in the United States with PAH have a median survival time of approximately three years from diagnosis.

About APD811

APD811, a potent and selective agonist (or activator) of the prostacyclin receptor, is our internally discovered drug candidate for the treatment of PAH. Prostacyclin receptor agonists, through regulation of vascular smooth muscle tone, improve mortality and 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 routes. We believe that APD811, as a non-prostanoid prostacyclin agonist, has the potential to improve the standard of care for PAH by providing an oral form of administration with clinical benefits similar to currently available prostacyclin receptor agonists.

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 prostacyclin receptor agonists in general, including with regard to improving treatment; and the protocol, design, scope, enrollment, and other aspects of the Phase 1 clinical trial for APD811. 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 risk that regulatory authorities may not

find data and other information related to our clinical trials and other studies meet safety or efficacy requirements or are otherwise sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; our response to the complete response letter for the lorcaserin NDA may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request additional information prior to approval of the lorcaserin NDA; unexpected 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 we or others expect 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: December 13, 2010

Arena Pharmaceuticals, Inc.

By: /s/ Steven W. Spector
Steven W. Spector

Senior Vice President, General Counsel and Secretary