ARENA PHARMACEUTICALS INC
Form 8-K
October 12, 2012

**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 12, 2012**

**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., the context otherwise provides.

**Item 8.01 Other Events.**

On October 12, 2012, we announced the initiation of dosing in a Phase 1 multiple dose clinical trial of APD811, a novel oral drug candidate we discovered that targets the prostacyclin, or IP, receptor for the treatment of pulmonary arterial hypertension, or PAH.

This randomized, double-blind and placebo-controlled dose titration trial is planned to enroll up to 30 healthy adult volunteers, and will evaluate the safety, tolerability and pharmacokinetics of multiple-ascending doses of APD811 and the optimal titration schedule. We previously evaluated single-ascending doses of APD811 in the initial Phase 1 clinical trial.

**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 strains the heart, which can limit physical activity, result in heart failure and reduce life expectancy. Based on data from the Registry to EValuate Early And Long-term PAH disease management, or REVEAL, of patients in the United States, there is an estimated five-year survival rate of 57% from diagnosis.

**About APD811**

APD811, an orally available agonist of the IP receptor, is an investigational drug candidate discovered by us and intended for the treatment of PAH. Treatment with IP agonists, which can slow disease progression and improve exercise tolerance in PAH patients, is considered standard of care for advanced PAH. Currently available IP 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 available, non-prostanoid IP agonist that provides clinical benefits similar to currently available IP 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 protocol, design, scope, enrollment, potential results and other aspects of the Phase 1 multiple dose clinical trial of APD811; and the potential of APD811 and orally available, non-prostanoid IP agonists in general. 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: APD811 may not have an adequate safety margin or otherwise be sufficient for further development or regulatory review or approval; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the pace of market acceptance; cash and revenues generated from lorcaserin, including the timing and impact of competition; the timing and outcome of regulatory review is uncertain; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; the entry into or modification or termination of collaborative arrangements; unexpected or unfavorable new data; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than us, request additional information, have additional recommendations or change their guidance or requirements before or

after approval; data and other information related to any of our research and development programs may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for regulatory review, approval or continued marketing; our ability to obtain and defend 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; having adequate funds; and satisfactory resolution of 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: October 12, 2012

Arena Pharmaceuticals, Inc.

By: /s/ Jack Lief
Jack Lief
President and Chief Executive Officer