ARENA PHARMACEUTICALS INC
Form 8-K
January 12, 2015

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): January 12, 2015

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.)**

6154 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., one or more of our wholly owned subsidiaries, unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc. BELVIQ® is a registered trademark of our wholly owned subsidiary, Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

On January 12, 2015, we announced the initiation of patient dosing in a Phase 2 clinical trial of ralinepag, an oral, non-prostanoid prostacyclin, or IP, receptor agonist intended for the treatment of pulmonary arterial hypertension, or PAH. The 22-week, randomized, double-blind and placebo-controlled Phase 2 trial will evaluate the hemodynamic and exercise capacity effects, safety and tolerability of ralinepag in up to 60 patients with PAH. During the first nine weeks of the trial, patients will be titrated to their individual tolerance level and then sustained at this level for the remainder of the trial.

About Pulmonary Arterial Hypertension

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 (REVEAL) of patients in the United States, there is an estimated five-year survival rate of 57% from diagnosis.

About Ralinepag

Ralinepag, an orally available agonist of the IP receptor, is an investigational drug candidate internally discovered and developed by us and intended for the treatment of vascular diseases, including PAH. In Phase 1 trials, ralinepag showed an approximate 25-hour half-life, indicating that the compound could be dosed once or twice daily. We believe that an orally available, non-prostanoid IP receptor agonist that provides clinical benefits similar to currently available IP receptor agonists has the potential to improve treatment for patients with PAH. The FDA has granted ralinepag orphan drug status for the treatment of 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, evaluation, therapeutic indication, use, safety, efficacy, dosing, mechanism of action, significance and potential of ralinepag, including relative to other therapies; the protocol, design, scope, enrollment, expectations and other aspects of the Phase 2 clinical trial of ralinepag; and potential of an orally available, non-prostanoid IP receptor agonist that provides clinical benefits similar to available IP receptor agonists. 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: ralinepag may not be developed, approved for marketing or commercialized for any disease or condition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ, including the impact of competition; our revenues will be based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to our guidance or previously reported results; the timing and outcome of regulatory review is uncertain, and BELVIQ may not be approved for marketing when expected or ever in combination with another drug, for another indication or using a different formulation or in any other territory for any indication; regulatory decisions in one territory may impact other regulatory decisions and our business prospects; government and commercial reimbursement and pricing decisions; risks related to relying on

collaborative arrangements; 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 or others, 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 may not meet regulatory requirements or otherwise be sufficient for (or we or a collaborator may not pursue) further research and

development, regulatory review or approval or continued marketing; our and third parties intellectual property rights; the timing, success and cost of our research and development; 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: January 12, 2015

Arena Pharmaceuticals, Inc.

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