ARENA PHARMACEUTICALS INC
Form 8-K
March 27, 2014

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 27, 2014

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.

Initiation of Investigational Phase 2 Clinical Trial of Lorcaserin for Smoking Cessation

We and Eisai have initiated an investigational Phase 2 clinical trial to evaluate lorcaserin hydrochloride as a potential aid to smoking cessation. The 12-week, randomized, double-blind and placebo-controlled Phase 2 trial will enroll approximately 600 active smokers. Patients will receive smoking cessation counseling throughout the trial, and will be randomized to one of three treatment arms in a 1:1:1 ratio: lorcaserin 10 mg once daily, lorcaserin 10 mg twice daily, or placebo. The primary outcome measure for the trial will assess if patients are able to maintain abstinence from cigarette smoking for the last four weeks of treatment, also known as the continuous quit rate. Eisai and we will share the cost of this trial under our Second Amended and Restated Marketing and Supply Agreement.

Internally discovered at Arena, lorcaserin is believed to selectively activate serotonin 2C receptors in the brain. Preclinical data suggest that serotonin 2C receptors may modulate the mesolimbic dopaminergic reward system, which may play a role in addiction to nicotine. The exact mechanism of action of lorcaserin is not known.

Lorcaserin is an investigational product for smoking cessation. The efficacy and safety of lorcaserin for smoking cessation have not been established.

Prevalence and Cost of Smoking

According to the US Department of Health and Human Services, or HHS, the epidemic of smoking-caused disease in the twentieth century ranks among the greatest American public health catastrophes of the century. Furthermore, unacceptably high levels of smoking-attributable disease and death, and the associated costs, will persist for decades without changes in the approach to slowing and even ending the epidemic. HHS reports that annual smoking-attributable economic costs in the United States estimated for the years 2009 2012 were between $289 332.5 billion, including for direct medical care of adults and lost productivity.

According to the Centers for Disease Control and Prevention, or CDC, cigarette smoking remains the leading cause of preventable disease and death in the United States, killing nearly half a million Americans each year. The CDC reports that, in 2012, approximately 42 million US adults were current cigarette smokers, and the CDC s analysis of 2010 survey data found that nearly 70% of US smokers wanted to completely stop smoking.

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 evaluation and potential of lorcaserin as an aid to smoking cessation; the related Phase 2 clinical trial of lorcaserin, including the protocol, design, scope, enrollment, cost sharing and other aspects of the trial; the prevalence and costs of smoking, and the need for a change in approach in this area; serotonin 2C receptors and the relation to addiction to nicotine; and lorcaserin s mechanism of action. 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: lorcaserin may not be a safe or efficacious aid to smoking cessation or ever be approved by a regulatory authority for such indication; 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 ability to obtain and defend patents; 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: March 27, 2014

Arena Pharmaceuticals, Inc.

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