ARENA PHARMACEUTICALS INC
Form 8-K
October 30, 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): October 30, 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 7.01 Regulation FD Disclosure.

Data and other information regarding lorcaserin will be presented at The Obesity Society s Annual Scientific Meeting during ObesityWeek taking place November 2-7, 2014, in Boston, Massachusetts. We expect that abstracts of presentations will be made available to meeting attendees, participants and certain others beginning later today. Among other data and information, data and information are expected to be presented from Eisai Inc. s pilot study to assess lorcaserin when coadministered with phentermine. Following is a copy of the abstract we expect will be provided for such presentation:

Title: Combination Weight Management (WM) Pharmacotherapy with Lorcaserin (LOR) and Immediate Release (IR) Phentermine (phen)

Authors:

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Background:

Pharmacotherapy for WM may involve combining drugs targeting different signaling pathways. This pilot study was sized to assess the primary outcome of impact of LOR, a specific $5HT_{2c}$ receptor agonist and phen on pre-selected potentially serotonergic (5HT) adverse events (AEs) compared to LOR alone.

Methods:

238 patients (pts) with BMI >30, or >27 with a comorbidity, but without T2DM, were randomized in a 12-week study comparing LOR 10mg BID alone, LOR 10mg BID with phenIR 15mg QD (LOR/phen QD) and LOR 10mg BID with phenIR 15mg BID (LOR/phen BD). All received a standard diet and exercise program with adherence self-reported by study subjects. The primary endpoint evaluated whether short-term LOR/phen treatment is associated with exacerbation of potential 5HT AEs compared to LOR alone. Secondary objectives included safety, tolerability, pharmacokinetics and weight loss (WL).

Results:

37.2% (LOR), 42.3% (LOR/phen QD), and 40.5% (LOR/phen BD) pts reported potential 5HT AEs. 5.1% (LOR), 2.6% (LOR/phen QD) and 10.1% (LOR/phen BD) pts discontinued due to AEs. At wk 12 mean changes in BP (systolic/diastolic) and pulse (bpm) were -5.5/-2.5/-1.9 (LOR), -3.3/-1.4/1.1 (LOR/phen QD) and -3.4/-1.7/3.1 (LOR/phen BD). Mean change from baseline WL (kg/%) in 12-wk completers was 4.0/3.8 (LOR), 7.6/7.3 (LOR/phen QD) and 8.9/8.7 (LOR/phen BD). 33.3% (LOR), 68.2% (LOR/phen QD) and 84.2% (LOR/phen BD) pts achieved ³5% WL (12-wk completers).

Conclusion:

Treatment with LOR plus phen was not associated with exacerbation of potential 5HT AEs compared to LOR alone. Common AEs during the trial were consistent with prior experience with these agents. The combination of LOR BID and phen BID more than doubled weight loss achieved compared to LOR alone.

Keywords: Lorcaserin, phentermine, safety

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 data and other information regarding lorcaserin, including their distribution and presentation. 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: top-line results are not comprehensive and are based on a preliminary analysis of then available data, and findings and conclusions related to the trial are subject to change following a more comprehensive review of the data; 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: October 30, 2014

Arena Pharmaceuticals, Inc.

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