ARENA PHARMACEUTICALS INC
Form 8-K
July 19, 2016

**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): July 14, 2016**

**Arena Pharmaceuticals, Inc.**

**(Exact name of registrant as specified in its charter)**

| | | |
|---|---|---|
| **Delaware** | **000-31161** | **23-2908305** |
| **(State or other jurisdiction** | **(Commission** | **(I.R.S. Employer** |
| **of incorporation)** | **File Number)** | **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®, BELVIQ XR® and VENESPRI® are registered trademarks of Arena Pharmaceuticals GmbH.

**Item 8.01 Other Events.**

Approval of BELVIQ XR® (lorcaserin HCl) Extended Release Tablets in the United States

On July 19, 2016, Eisai Inc. and we announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for BELVIQ XR® (lorcaserin HCl) extended release tablets 20 mgs CIV for chronic weight management in the United States. The new formulation will offer patients a once-a-day dosing option. BELVIQ XR will be available in the fall of 2016. In connection with the approval, Arena will receive a $10 million milestone payment.

Approval of VENESPRI® in Mexico

On July 14, 2016, Eisai and we announced the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) granted regulatory approval of the twice-daily formulation of lorcaserin hydrochloride for chronic weight management in Mexico. Lorcaserin will be marketed under the brand name VENESPRI® in Mexico. In connection with the approval, Arena will receive a $1 million milestone payment.

**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 therapeutic indication and potential of BELVIQ, BELVIQ XR and VENESPRI; the marketing and expected availability of BELVIQ XR and VENESPRI; and milestone payments. 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: risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and the availability and use of BELVIQ, BELVIQ XR and VENESPRI; disagreements with our collaborators; cash and revenues generated from BELVIQ, BELVIQ XR and VENESPRI; we may need additional funds to advance all of its programs, and you may not agree with the manner we allocate our resources; the risk that our revenues are 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 lorcaserin (immediate or extended release) may not receive any additional marketing approvals; 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 and related strategy and decisions; 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; 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 Arena s 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 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 Exch ange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 18, 2016

Arena Pharmaceuticals, Inc.

By: /s/ Amit Munshi
Amit Munshi
President and Chief Executive Officer