ARENA PHARMACEUTICALS INC
Form 8-K
December 05, 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): December 5, 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.

BELVIQ US Regulatory Update

Eisai Inc. and we have discovered that a small number of bottles of BELVIQ in a limited number of lots had a missing or incomplete label. This labeling issue relates to the packaging of BELVIQ and not the tablets.

As a precautionary measure, Eisai voluntarily initiated today a recall from wholesalers of the involved lots for inspection. Eisai will restock this inventory, and it does not anticipate any supply interruption at the retail level. Eisai considers this a class III recall, which includes product recalled because of a defect that is unlikely to cause patient harm, but causes the product to be non-compliant with marketing authorizations or specifications.

BELVIQ Canada Regulatory Update

As previously reported, Health Canada s Therapeutics Product Directorate issued a Notice of Deficiency regarding Eisai s new drug submission for approval of BELVIQ for marketing in Canada. Health Canada informed Eisai that the new drug submission contains deficiencies that must be addressed for the review of the new drug submission to continue. Eisai determined that the development of a complete response would require more time than allotted and has withdrawn the new drug submission. Eisai informed us that it plans to resubmit a new drug submission once it believes it has satisfactorily addressed the items outlined in the Notice of Deficiency.

BELVIQ Israel Regulatory Update

Teva Pharmaceutical Industries Limited s local Israeli subsidiary, Abic Marketing Limited, has filed for marketing authorization of BELVIQ in Israel. In connection with the filing, we will receive a milestone payment of $250,000.

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 a recall involving BELVIQ, including the class, timing, scope and significance of the recall; the restocking of inventory and the supply and impact at the retail level; responding to the Notice of Deficiency relating to the previous new drug submission for approval of BELVIQ in Canada, including developing a satisfactory response and resubmitting for approval of BELVIQ in Canada; and the potential approval of BELVIQ in Israel and the receipt of a milestone payment for the related regulatory filing. 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: the timing, scope and significance of the recall by Eisai may change, including the final classification of the class of the recall; 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; 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; 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: December 5, 2014

Arena Pharmaceuticals, Inc.

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