

ARENA PHARMACEUTICALS INC

Form 8-K

January 10, 2012

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 10, 2012

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-31161
(Commission

File Number)

6166 Nancy Ridge Drive, San Diego, California 92121

23-2908305
(I.R.S. Employer

Identification No.)

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(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., unless the context otherwise provides.

Item 8.01 Other Events.

On January 10, 2012, we and Eisai Inc. announced that the US Food and Drug Administration, or FDA, has accepted for filing and review our resubmission of the New Drug Application, or NDA, for lorcaserin. The FDA considers the resubmission a complete, class 2 response, and assigned a new Prescription Drug User Fee Act, or PDUFA, target date of June 27, 2012.

Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (Body Mass Index, or BMI, ≥ 30) or patients who are overweight (BMI ≥ 27) and have at least one weight-related co-morbid condition.

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, therapeutic indication and use, and potential of lorcaserin; and the resubmission of the lorcaserin NDA, including the FDA's review and the potential timing for the FDA to complete such review. 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 of regulatory review and approval is uncertain, and the FDA may not complete its review of the resubmission of the lorcaserin NDA by the PDUFA date; 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 we or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; data and other information related to lorcaserin and our other research and development programs may not meet safety or efficacy requirements or otherwise be sufficient for regulatory review or approval; our submission of a marketing authorization application for regulatory approval of lorcaserin may not be submitted when anticipated, if at all; unexpected or unfavorable new data; risks related to commercializing new products; our ability to obtain and defend our patents; the timing, success and cost of our research and development programs; 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; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; and satisfactory resolution of pending and any future 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 10, 2012

Arena Pharmaceuticals, Inc.

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