ARENA PHARMACEUTICALS INC
Form 8-K
October 25, 2010

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 22, 2010

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.)**

6166 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., unless the context otherwise provides.

Item 8.01 Other Events.

On October 22, 2010 (Pacific Time), we announced that the US Food and Drug Administration, or FDA, issued a Complete Response Letter, or CRL, regarding our New Drug Application, or NDA, for lorcaserin. 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.

The FDA has completed its review of the NDA and determined that it cannot approve the application in its present form. In the CRL, FDA outlined the non-clinical and clinical reasons for their decision.

The non-clinical issues identified by the FDA included diagnostic uncertainty in the classification of mammary masses in female rats, unresolved exposure-response relationship for lorcaserin-emergent mammary adenocarcinoma, and unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma.

The CRL included the following requests related to the non-clinical issues: provide a detailed accounting of all slides prepared from female rats that contributed to mammary tumor incidence data in each update to the FDA and to the final study report; in consultation with the FDA, identify an independent pathologist or group of pathologists to re-adjudicate all mammary and lung tissues (neoplastic and nonneoplastic lesions) from all female rats; demonstrate that the apparent increase in aggressiveness of adenocarcinoma in rats administered lorcaserin is reasonably irrelevant to human risk assessment; and provide additional data/information regarding the distribution of lorcaserin to the CNS in animals and human subjects that would clarify or provide a better estimate of astrocytoma exposure margins.

With respect to the clinical reasons, the FDA stated in the CRL that the weight loss efficacy of lorcaserin in overweight and obese individuals without type 2 diabetes is marginal and recommended that we submit the final study report of the BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. The FDA also stated in the letter that in the event evidence cannot be provided to alleviate concern regarding clinical relevance of the tumor findings in rats, additional clinical studies may be required to obtain a more robust assessment of lorcaserin s benefit-risk profile.

The BLOOM-DM trial evaluated lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes mellitus. We expect to announce top-line results for the trial in the next few weeks and to have a completed study report by the end of the year.

The FDA stated in the CRL that it would recommend placement of lorcaserin in Schedule IV of the Controlled Substance Act based on its review of the materials submitted in the NDA. The CRL provided the opportunity to complete preclinical studies that may lead to a different recommendation. In addition, the FDA requested in the CRL that we include a safety update in our response that includes data from all nonclinical and clinical studies/trials of lorcaserin.

We intend to request a Type A meeting with the FDA to clarify its requests, and, if the meeting is granted, the FDA s guidance states that it should occur within 30 days of the request.

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 future activities related to the complete response letter, including meeting with the FDA, and the outcome of such meeting; BLOOM-DM, including the announcement of top-line results and the completion of the related study report; and the advancement, therapeutic indication and use, safety, efficacy, tolerability, mechanism of action, scheduling and regulatory review and approval of lorcaserin. 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 risk that regulatory authorities may not find data from our clinical trials and other studies sufficient for regulatory approval; regulatory review and approval is uncertain; our response to the complete response letter may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request additional information or have additional recommendations prior to approval, if any; unexpected new data; our ability to obtain and defend our patents; risks related to commercializing new products; the timing, results and cost of clinical trials, preclinical studies and research activities; 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 we or others expect or at all; our ability to obtain adequate funds; unfavorable decisions by Eisai Inc. and our other collaborators relating to our collaborations; the timing and receipt of payments and fees, if any, from Eisai Inc. and our other 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 report. 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 25, 2010

Arena Pharmaceuticals, Inc.

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