ARENA PHARMACEUTICALS INC
Form 8-K
December 23, 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): December 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 December 22, 2010, we announced the completion of our end-of-review meeting with the US Food and Drug Administration, or FDA, for the lorcaserin New Drug Application, or NDA. The end-of-review meeting with the FDA included discussion on the FDA s position on issues identified in the Complete Response Letter, or CRL, it issued us in October 2010 and our plan to respond to the CRL. Our plan to respond includes initiating several preclinical studies and a small clinical trial, and we expect to resubmit the lorcaserin NDA to the FDA by the end of 2011.

The preclinical studies, clinical trial and other activities we plan to conduct for our response to the CRL relate to addressing the following issues identified by the FDA in the CRL: diagnostic uncertainty in the classification of mammary masses in female rats; unresolved exposure-response relationship for lorcaserin-emergent mammary adenocarcinoma; unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma; the efficacy of lorcaserin; and the scheduling of lorcaserin. We expect that the aggregate external costs for such preclinical studies and clinical trial will not exceed a few million dollars. As part of our response, we plan to submit the final study report for our BLOOM-DM trial to the FDA along with analyses integrating or pooling data from our BLOOM-DM trial with data from our BLOOM and BLOSSOM trials.

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 our plan to respond to the CRL, elements of such plan, expected costs, the potential resubmission of the lorcaserin NDA, and the related timing. 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 risk that regulatory authorities may not find data and other information related to our clinical trials and other studies meet safety or efficacy requirements or are otherwise sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; our response to the complete response letter for the lorcaserin NDA may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request other information prior to or after we resubmit the lorcaserin NDA or approval of the lorcaserin NDA; unexpected or unfavorable new data; risks related to commercializing new products, including with regard to scheduling; 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 we or others expect or at all; our ability to obtain 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: December 23, 2010

Arena Pharmaceuticals, Inc.

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