

ARENA PHARMACEUTICALS INC

Form 8-K

September 16, 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): September 16, 2010

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-31161
(Commission

File Number)

23-2908305
(I.R.S. Employer

Identification No.)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

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 September 16, 2010, we announced that the US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee voted 9 to 5 that the available data do not adequately demonstrate that the potential benefits of lorcaserin outweigh the potential risks when used long-term in a population of overweight and obese individuals to allow marketing approval. Lorcaserin, which Arena discovered and has developed, 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.

Although advisory committees provide recommendations to the FDA, the agency makes the final decisions. The FDA has assigned a PDUFA date, the target date for the agency to complete its review of the lorcaserin New Drug Application (NDA), of October 22, 2010.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the potential benefits, risks, therapeutic indication and regulatory process and approval of lorcaserin. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's 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 Arena's clinical trials and other studies sufficient for regulatory approval; the timing of any regulatory review and approval is uncertain; risks related to commercializing new products; and results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims 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: September 16, 2010

Arena Pharmaceuticals, Inc.

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