

ARENA PHARMACEUTICALS INC
Form 8-K
February 24, 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): February 24, 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)

6166 Nancy Ridge Drive, San Diego, California 92121

(Address of principal executive offices) (Zip Code)

23-2908305
(I.R.S. Employer

Identification No.)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

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, we, us and our refer to Arena Pharmaceuticals, Inc., and its wholly owned subsidiaries, unless context otherwise provides.

Item 8.01 Other Events.

On February 24, 2010, we announced that our New Drug Application, or NDA, for lorcaserin, our internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss, has been accepted for filing by the US Food and Drug Administration, or FDA. We submitted the lorcaserin NDA on December 22, 2009, and expect to learn the Prescription Drug User Fee Act, or PDUFA, date in the next few weeks. The PDUFA date is the target date for the FDA to complete its review of an NDA.

The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.

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 development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy and regulatory review and approval of lorcaserin; and future activities and events relating to lorcaserin, including the receipt of a PDUFA date. 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, regulatory authorities may not find data from our clinical trials and other studies sufficient for regulatory approval; the timing and our ability to receive regulatory approval for our drug candidates; the timing, success and cost of our lorcaserin program and other 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 expect or at all; our ability to partner or commercialize lorcaserin or other of our compounds or programs; our ability to obtain adequate funds; our ability to obtain and defend our patents; and the timing and receipt of payments and fees, if any, from our collaborators. 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: February 24, 2010

Arena Pharmaceuticals, Inc.

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