ARENA PHARMACEUTICALS INC
Form 8-K
August 11, 2011

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): August 9, 2011

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 August 9, 2011, we announced results from a Pathology Working Group s, or PWG, re-adjudication of female rat mammary tumor diagnoses from a two-year rat carcinogenicity study of lorcaserin. We convened the PWG in response to the lorcaserin Complete Response Letter, or CRL, which questioned the certainty of the female rat mammary tumor classifications. The PWG reviewed relevant tissues and reported that mammary fibroadenomas (benign tumors) were distinguishable from mammary adenocarcinomas (malignant tumors). The PWG reported shifts in the numbers of both tumor types from the initial report included in the lorcaserin New Drug Application, or NDA, and that adenocarcinomas were no longer numerically higher than the control group in the lorcaserin low- and mid-dose groups.

The PWG s re-adjudication is one of the activities intended to address the observation of mammary tumors in female rats and is part of the overall plan to submit a response to the lorcaserin CRL. Additional activities intended to address the CRL are ongoing.

Findings from Initial and PWG Reports

The PWG consisted of five pathologists contracted by us. We consulted the US Food and Drug Administration, or FDA, in selecting these pathologists. According to the PWG s re-adjudication, the incidence of adenocarcinomas was numerically lower than the control group in both the lorcaserin low (10 mg/kg/day) and mid (30 mg/kg/day) dose groups and was statistically higher than the control group in the lorcaserin high (100/kg/day) dose group, and the incidence of fibroadenomas was statistically higher than the control group for all three lorcaserin dose groups. The incidences of adenocarcinomas and fibroadenomas from the initial report and the PWG report are summarized below.

Percent of Female Rats with Mammary Adenocarcinoma or Fibroadenoma

Dose	Control	10 mg/kg/day	30 mg/kg/day	100 mg/kg/day
N	65	65	65	75
Mammary Adenocarcinoma (Malignant)				
Initial Report	43.1%	52.3%	53.9%	80.0%
PWG Report	40.0%	32.3%	36.9%	68.0%
Mammary Fibroadenoma (Benign)				
Initial Report	30.8%	72.3%	81.5%	60.0%
PWG Report	36.9%	83.1%	84.6%	68.0%

In addition, the PWG reported that the incidence of mammary adenomas (benign tumors) was 1.5%, 3.1%, 7.7%, 5.3%, the incidence of mammary carcinosarcomas (malignant tumors) was 0%, 0%, 0%, 1.3%, the incidence of lung metastases of mammary gland origin was 0%, 1.5%, 7.7%, 6.7%, and the incidence of lung metastases of non-mammary gland origin was 0%, 4.6%, 6.2%, 2.7% for the control and lorcaserin low-, mid- and high-dose groups, respectively. No mammary adenomas were diagnosed in the initial report, the incidence of mammary carcinosarcomas did not change from the initial report, and the incidence of lung metastases of both mammary and non-mammary origin were reported together in the initial report as 0%, 6.2%, 13.8% and 8.0% for the control and lorcaserin low-, mid- and high-dose groups, respectively.

Based on the PWG s diagnoses and our analyses, neither time to onset nor tumor multiplicity for adenocarcinoma statistically differed from the control group at the lorcaserin low- and mid-dose groups; time to onset statistically decreased and tumor multiplicity statistically increased at the lorcaserin high-dose group as compared to the control group. Also based on the PWG s diagnoses and our analyses, time to onset statistically decreased and tumor multiplicity statistically increased for fibroadenoma for all three lorcaserin dose groups as compared to the control group.

It is important to note that the FDA may have a different interpretation of the re-adjudication and subsequent conclusions of the PWG. There may be other factors in addition to incidence that may contribute to the FDA s assessment of human risk for the finding of mammary tumors in female rats. The information reported in this Form 8-K summarizes a report containing voluminous and detailed data that will be reviewed by the FDA. The FDA may analyze or weigh the importance of data from the report differently than the PWG or us.

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, safety, efficacy, tolerability, mechanism of action and potential of lorcaserin; the significance of the PWG s re-adjudication and report, including in assessing human risk and addressing the female rat mammary tumor diagnoses; the FDA s assessment of human risk, analysis and weighting of data and interpretation of the PWG s re-adjudication, report and findings; and the response to the CRL for the lorcaserin NDA, including related plans and activities. 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 FDA may not accept the PWG s re-adjudication, report or findings, may interpret and analyze the data differently and may reach different conclusions; the timing of regulatory review and approval is uncertain; the risk that data and other information related to our research and development programs may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; our response to the CRL for the lorcaserin NDA or submission of a Marketing Authorization Application for regulatory approval of lorcaserin may not be submitted when anticipated, if at all; the FDA may request other information prior to or after we submit such response or approval of the lorcaserin NDA; 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; 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: August 11, 2011

Arena Pharmaceuticals, Inc.

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