ARENA PHARMACEUTICALS INC
Form 8-K
January 28, 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): January 27, 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 2.05 Costs Associated with Exit or Disposal Activities.

On January 27, 2011, we committed to a reduction of our US workforce of approximately 25%, or 66 employees. As a result of the workforce reduction, which we plan to complete around March 28, 2011, we expect to incur restructuring charges, primarily in the first quarter of 2011, of approximately $3.8 million in connection with one-time employee termination costs, including severance and other benefits. We expect the reduction to decrease annualized cash expenditures by approximately $13.5 million.

Recent regulatory actions affecting lorcaserin caused us to revise our corporate strategy and to reduce our expenditures, including through this workforce reduction. We intend to focus our resources on working to obtain regulatory approval of lorcaserin, seeking collaborators for the commercialization of lorcaserin outside of the US and advancing select earlier-stage research and development programs independently or in partnership. We plan to complete this year the ongoing Phase 1a clinical trial for APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, and advance APD334, an agonist of the S1P1 receptor intended for the treatment of multiple sclerosis, toward clinical development. We also plan to explore exclusive partnering opportunities for our broad array of internally discovered, oral GPR119 agonists, including APD597 and next-generation compounds, and non-exclusive partnering opportunities for our portfolio of patents and patent applications related to the discovery and development of GPR119 receptor agonists.

We expect to provide additional details on the financial impact of these changes when we report results for the fourth quarter and full year ended December 31, 2010.

Item 8.01 Other Events.

In December 2010, we reported on our discussions with the US Food and Drug Administration, or FDA, at the end-of-review meeting for the lorcaserin New Drug Application, or NDA, including our and Eisai s plans to address the lorcaserin Complete Response Letter, or CRL, and the expectation to resubmit the NDA to the FDA by the end of 2011. We are continuing our discussions with the FDA to finalize protocols for activities that are designed to address the issues raised by the FDA or that otherwise are related to the assessment of the benefit-risk profile of lorcaserin. The FDA has requested that we submit protocols prior to initiating certain studies and expects to provide us with its comments and recommendations within approximately one month of each protocol submission.

As previously announced, the majority of activities relate to the three non-clinical issues outlined in the CRL. The first issue relates to the diagnostic uncertainty in the classification of mammary masses in female rats. As part of addressing this issue, we have convened five independent pathologists to re-adjudicate the female rat mammary tumor diagnoses from the rat carcinogenicity study. The FDA has reviewed and agreed to our protocol, and this work is ongoing.

The second issue relates to demonstrating a mechanism for mammary adenocarcinoma in female rats that is reasonably irrelevant to human risk. We are planning experiments to further test the theory that lorcaserin causes mammary tumors in rats by increasing prolactin. The FDA has recommended a dosing duration of no less than three months to establish a causal relationship between lorcaserin, prolactin elevation and mammary tumor development in rats. Subsequent to the end-of-review meeting, the FDA requested that we consider performing a separate 12-month study in female rats that would test whether transient prolactin elevation mediated by short-term exposure to lorcaserin can result in mammary tumors in rats.

The third issue relates to the unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma in male rats. Because the mechanism for induction of astrocytomas in rats is unknown, we will focus on providing additional information designed to demonstrate that an adequate safety margin exists for humans. We plan to conduct non-clinical experiments, including receptor pharmacology studies, and a small clinical study to measure lorcaserin concentrations in human cerebrospinal fluid to provide additional data that may be informative for predicting human brain levels at therapeutic doses of lorcaserin. At the FDA s recommendation subsequent to the end-of-review meeting, we will expand the receptor studies to more fully characterize lorcaserin s activity at the 5-HT_{2B} receptor to further assess the risk of valvulopathy.

In addition, the FDA has expressed concern over the abuse potential of lorcaserin and the available data related to abuse potential, and has recommended that we modify and repeat two non-clinical studies to provide additional safety information for labeling and scheduling decisions. We are preparing to initiate these studies pending a meeting that is scheduled to take place with the Controlled Substances Staff in February.

We are working to address the FDA s concerns and continue to believe that we can resubmit the lorcaserin NDA by the end of 2011. We are in continuing discussions with the FDA, and it is possible that certain activities may be required that could impact the timeline for resubmission or potential FDA approval of lorcaserin.

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 reduction of our workforce, including the expected size, timing, related charges and benefits, and other expected impact of such reduction; future research, development, regulatory and partnering focus, plans and activities; partnering opportunities and the advancement and potential of our programs; discussions with the FDA and the results of such discussions; submission of protocols to the FDA and the FDA s response; ongoing and future studies and activities to address the CRL and the FDA s concerns and requests; the potential resubmission of the lorcaserin NDA and the related timing; the advancement, therapeutic indication and use, safety, efficacy, tolerability, and mechanism of action of lorcaserin; and the Eisai collaboration and potential activities thereunder. 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 negative effects related to the reduction

of our workforce may be greater than anticipated; the risk that we may not realize the benefits expected from such reduction; 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 CRL for the lorcaserin NDA may not be submitted when anticipated 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; 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: January 27, 2011

Arena Pharmaceuticals, Inc.

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