ARENA PHARMACEUTICALS INC
Form 8-K
May 10, 2012

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): May 9, 2012

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 1.01 Entry into a Material Definitive Agreement.

On May 9, 2012, our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, and Eisai Inc., or Eisai, entered into an Amended and Restated Marketing and Supply Agreement, or the Amended Agreement, which amends the Marketing and Supply Agreement, or Original Agreement, the parties entered into in July 2010. The Original Agreement provided Eisai exclusive rights to commercialize lorcaserin in the United States and its territories and possessions, subject to the approval by the U.S. Food and Drug Administration, or FDA, of our New Drug Application, or NDA, for lorcaserin. The Amended Agreement expands the territories such that Eisai now also has exclusive rights to commercialize lorcaserin in most of North and South America (including Canada, Mexico and Brazil), or Additional Territories, subject to applicable regulatory approval.

As in the Original Agreement, Arena GmbH will manufacture lorcaserin at its facility in Switzerland, and Eisai will purchase all of its requirements of lorcaserin from Arena GmbH. Arena GmbH will sell lorcaserin to Eisai for marketing and distribution in the United States and in the Additional Territories for a purchase price starting at 31.5% and 30.75%, respectively, of Eisai s aggregate annual net product sales in all of the territories on an aggregate basis. The purchase price will increase on a tiered basis in the United States and in the Additional Territories to as high as 36.5% and 35.75%, respectively, on the portion of Eisai s annual net product sales exceeding $750 million, subject to reduction (for sales in a particular country) in the event of generic competition in the applicable country. The Amended Agreement includes certain payments by Eisai if certain annual minimum sales requirements in the Additional Territories are not met during the first ten years after initial commercial sale in Canada, Mexico or Brazil.

Arena GmbH s eligibility to receive up to an aggregate of $1.19 billion in one-time purchase price adjustment and other payments based on Eisai s annual net sales of lorcaserin in the United States under the Original Agreement will now be based on the annual net sales of lorcaserin in the United States and the Additional Territories on an aggregate basis, with the first and last amounts payable, as they were under the Original Agreement, with annual net sales of $250 million and $2.5 billion, respectively. Of these payments, Eisai will pay Arena GmbH a total of $330 million for annual net sales of up to $1 billion. Arena GmbH is also now eligible to receive up to an additional $185 million in one-time purchase price adjustment payments based on Eisai s annual net sales of lorcaserin in the Additional Territories, with the first and last amounts payable upon first achievement of annual net sales of $100 million and $1 billion in the Additional Territories, respectively.

In addition, under the Amended Agreement, we will receive from Eisai an upfront payment of $5 million, and an additional $5 million milestone payment upon regulatory approval of lorcaserin in, whichever may occur first, the United States or in a European Union country. Under the Amended Agreement, $4.5 million in additional regulatory and development milestone payments, based on achievement of regulatory filings or approvals in the Additional Territory, were also added, so that the total of such milestones (including those under the Original Agreement) is $74.5 million. In addition, the milestone payment due upon regulatory approval in the United States and delivery of product supply for launch continues to be $40 million or $60 million, depending on the approved drug label.

We are responsible for regulatory activities related to the lorcaserin NDA until transfer of the NDA to Eisai, and Eisai is responsible for regulatory activities related to the lorcaserin NDA thereafter as well as the regulatory activities for obtaining regulatory approval in any country in the Additional Territories.

With respect to the United States, if the FDA requires development work following approval of the lorcaserin NDA, Eisai will bear 90% and Arena GmbH will bear 10% of the expenses for such work, except that the parties will share equally the costs of certain pediatric or adolescent studies. If additional development work is required by the FDA prior to approval of the lorcaserin NDA, the parties will share equally the development expenses for such work. With respect to the Additional Territories, Eisai is responsible for most of the costs and expenses associated with seeking and obtaining regulatory approval in such territories. If the regulatory authority for a country in the Additional Territories requires development work before or following approval of lorcaserin in such country, Eisai will bear 90% and Arena GmbH will bear 10% of the expenses for such work, with the exception of the expenses for stability testing which will be shared equally by the parties.

The parties have agreed to not commercialize outside of the Amended Agreement any product that competes with lorcaserin in the United States or the Additional Territories. The Amended Agreement continues to include a stand-still provision limiting Eisai s ability to acquire Arena s or Arena GmbH s securities and assets.

Eisai may terminate the Amended Agreement with respect to the United States or any country in the Additional Territories following the later of the expiration of all issued lorcaserin patents in such country and 12 years after the first commercial sale of lorcaserin in such country. Either party has the right to terminate the Amended Agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for commercialization concerns, and (c) for certain intellectual property infringement. Eisai also has the right to terminate the Amended Agreement early in its entirety or with respect to each country in certain circumstances, including (i) termination in a country if sales of generic equivalents of lorcaserin in such country exceed sales of lorcaserin in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with lorcaserin. In addition, Arena GmbH can terminate the Amended Agreement early in its entirety or with respect to each country in the Additional Territories in certain circumstances, including termination in each country if Eisai does not satisfy certain regulatory filing and commercialization diligence requirements in such country.

Eisai will indemnify Arena GmbH for certain losses resulting from third-party claims, including for (a) Eisai s negligence, willful misconduct, or violation of law in performing under the Amended Agreement, (b) Eisai s defaults or breaches under the Amended Agreement or certain other agreements with Arena GmbH, (c) certain governmental investigations of Eisai, and (d) certain infringement claims related to trademarks selected by Eisai.

Arena GmbH will indemnify Eisai for certain losses resulting from third-party claims, including for (a) Arena GmbH s negligence, willful misconduct or violation of law with respect to development of lorcaserin prior to the effective date of the Original Agreement, (b) Arena GmbH s negligence or willful misconduct with respect to lorcaserin development and sale outside of the United States and the Additional Territories, (c) Arena GmbH s defaults or breaches under the Amended Agreement, (d) Arena GmbH s negligence, willful misconduct, or violation of law in performing under the Amended Agreement, (e) Arena GmbH s defaults or breaches under the Amended Agreement or certain other agreements with Eisai, and (f) certain intellectual property infringement, including infringement claims related to the manufacture of lorcaserin or to trademarks selected by Arena GmbH.

Arena GmbH will indemnify Eisai for losses resulting from third party product liability claims in the United States, except to the extent caused by Eisai s negligence, willful misconduct, violation of law or breach or default of the Amended Agreement or certain other agreements between the parties. In addition, each of Arena GmbH and Eisai will share equally in losses resulting from third party product liability claims in the Additional Territories, except to the extent caused by one party s negligence, willful misconduct, violation of law or breach or default of the Amended Agreement or certain other agreements between the parties.

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, regulatory review, approval, commercialization and potential of lorcaserin; rights and obligations under the Amended Agreement and the significance of such agreement; and expectations, goals and future activities related to the Amended Agreement, including the manufacture of lorcaserin, sale of finished product, future development and upfront, milestone, development and other payments. 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: risks related to the implementation and continuation of the Amended Agreement and dependence on collaborators; the timing and receipt of payments and fees, if any, from collaborators; the timing, results and impact of FDA advisory committee meetings relating to lorcaserin and other drug candidates; the timing of regulatory review is uncertain and our applications for regulatory approval of lorcaserin may not be reviewed when or as anticipated; the FDA may not complete its review of the lorcaserin NDA resubmission by the PDUFA date; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than we or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; data and other information related to lorcaserin and our other research and development programs may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for regulatory review or approval; 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; having adequate funds; and

satisfactory resolution of 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: May 10, 2012

Arena Pharmaceuticals, Inc.

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