ARENA PHARMACEUTICALS INC
Form 8-K
May 15, 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 15, 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)**	**(IRS Employer Identification No.)**

6166 Nancy Ridge Drive

San Diego, CA 92121

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: 858.453.7200

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.

We are filing the following information with the Securities and Exchange Commission for the purpose of updating certain aspects of our publicly disclosed description of our business and risk factors, as set forth below.

BUSINESS

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, or GPCRs, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. We have submitted regulatory applications for US and EU approval of our most advanced drug candidate, lorcaserin, which is intended for weight management. We intend to selectively advance certain of our research and development programs, and also to seek collaborators or other licensing opportunities for our programs.

In December 2011, we resubmitted to the US Food and Drug Administration, or FDA, a New Drug Application, or NDA, for lorcaserin. The FDA accepted the resubmission for filing and review and assigned a new Prescription Drug User Fee Act, or PDUFA, target date of June 27, 2012. Previously, in October 2010, the FDA issued a Complete Response Letter, or CRL, with respect to the original lorcaserin NDA we submitted in December 2009. In the CRL, the FDA stated that it had determined that it could not approve the application in its then present form.

On May 10, 2012, the FDA s Endocrinologic and Metabolic Drugs Advisory Committee met to discuss the lorcaserin NDA. The advisory committee voted 18 to 4, with one abstention, that the available data demonstrate that the potential benefits of lorcaserin outweigh the potential risks when used long-term in a population of overweight and obese individuals.

We are also seeking regulatory approval for lorcaserin in the European Union. On March 2, 2012, we filed a marketing authorization application, or MAA, for lorcaserin through the centralized procedure with the European Medicines Agency, or EMA. The EMA accepted the filing, which initiates the EMA s review process.

Our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, has provided Eisai Inc., or Eisai, exclusive rights to commercialize lorcaserin in most of North and South America, including the United States, Canada, Mexico and Brazil, subject to applicable regulatory approval. We have retained commercial rights to lorcaserin outside of North and South America, including in the European Union and Asia.

Our prioritized earlier-stage programs include APD811, an internally discovered, orally available agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension. APD811 completed a single-dose, Phase 1 clinical trial in 2011, and we plan to initiate a multiple dose, dose titration, Phase 1 clinical trial of APD811 this year. We also plan to file in 2012 an Investigational New Drug, or IND, application with the FDA for APD334 (an internally discovered, orally available agonist of the S1P1 receptor intended for the treatment of a number of conditions related to autoimmune diseases, including multiple sclerosis) and to continue development of our programs on APD371 (an internally discovered, orally available agonist of the cannabinoid receptor 2 intended for the treatment of pain) and GPR119 agonists (intended for the treatment of type 2 diabetes).

Along with lorcaserin and our prioritized earlier-stage programs, we have additional internally discovered oral drug candidates as well as active research programs intended to discover drug candidates. With respect to the additional drug candidates, we are not planning to conduct significant development activities, including any clinical trials, at this time. We may consider resuming their development in the future with one or more collaborators or independently, depending on the cost of further development, financial resources and their potential.

The headquarters of our operations outside of the United States is in Switzerland at Arena GmbH. Activities conducted at this location include manufacturing, quality control, quality assurance, development of manufacturing processes, qualifying suppliers and otherwise managing the global supply chain, regulatory compliance, distribution of finished products, and European strategic planning and development.

We have commercial rights for all of our programs and drug candidates, with the exception of Eisai s right to commercialize lorcaserin in most of North and South America. We have not received regulatory approval to market or sell any drugs or generated commercial revenues from selling any drugs, other than in connection with manufacturing drugs for Siegfried Ltd. in our Swiss drug product manufacturing facility.

RISK FACTORS

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information in this Current Report and in our other public filings before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Risks Relating to Our Business

We may not receive FDA approval for lorcaserin despite the recent vote of the FDA advisory committee.

In December 2011, we resubmitted the lorcaserin NDA, and the FDA subsequently accepted the NDA for filing. On May 10, 2012, the FDA s Endocrinologic and Metabolic Drugs Advisory Committee met to discuss the resubmitted NDA, and the committee voted 18 to 4, with one abstention, that the available data demonstrate that the potential benefits of lorcaserin outweigh the potential risks when used long-term in a population of overweight and obese individuals. The FDA is not bound by the recommendations of its advisory committees, but is expected to consider their guidance during the review of the NDA. The PDUFA target date for lorcaserin is June 27, 2012. There is no assurance that we will receive approval for lorcaserin on the PDUFA target date or ever. The FDA may decide not to approve lorcaserin, may issue another CRL, may extend the PDUFA target date or may take various other actions. If lorcaserin is not approved for commercial sale or if its development or approval is delayed for any reason, our full investment in lorcaserin may be at risk, the market price of our common stock could decline significantly, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms we or others believe are favorable, our ability to enter into additional collaborative agreements would likely decrease significantly, we may face costs associated with stopping development of lorcaserin, and our business and financial condition could be materially adversely affected.

Risks Relating to Our Securities

We have reserved for future issuance substantially all of our authorized but unissued shares of common stock, which may impair our ability to conduct future financing and other transactions.

Our certificate of incorporation currently authorizes us to issue up to 242,500,000 shares of common stock and 7,500,000 shares of preferred stock. As of May 10, 2012, we had a total of 184,500,778 shares of common stock outstanding. Of the remaining shares of common stock that were authorized but unissued, a substantial portion are reserved for future issuance pursuant to options outstanding under our equity incentive plans, shares issuable under our 2009 Long-Term Incentive Plan, shares issuable under our 2009 Employee Stock Purchase Plan, shares issuable under our Deferred Compensation Plan, and shares issuable under warrants to purchase shares of our common stock with an expiration date of June 17, 2015, a seven-year warrant issued in June 2006 to purchase shares of our common stock and a seven-year warrant issued in August 2008 to purchase shares of our common stock. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to further amend our certificate of incorporation to increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

In lieu of issuing common stock or securities convertible into or exercisable for shares of our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible into or exercisable for shares of our common stock, our ability to enter into strategic transactions, such as acquisitions of companies or technologies, may also be limited.

We are proposing to our stockholders at our June 2012 annual stockholders meeting to further amend our certificate of incorporation to increase the total number of our authorized shares from 250.0 million to 375.0 million and to increase the number of authorized shares of common stock from 242.5 million to 367.5 million. This proposal requires approval by the holders of a majority of our outstanding shares of common stock then entitled to vote, and we cannot assure you that such a proposal will be approved. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible into or exercisable for shares of our common stock, our financial condition and business prospects may be materially harmed.

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, mechanism of action and potential of lorcaserin; the regulatory review of lorcaserin regulatory filings; the potential approval and commercialization of lorcaserin; the collaboration with Eisai and activities thereunder; our plans to further amend our certificate of incorporation to increase our number of authorized shares; and our focus, goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. 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 timing of regulatory review is uncertain and our applications for regulatory approval of lorcaserin may not be reviewed when or as anticipated; the timing, results, influence and other impact of FDA advisory committee meetings relating to lorcaserin and other drug candidates; 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; even if any of our drug candidates is approved for marketing, such approval may be subject to limitations on the indicated uses, restricted distribution methods and other limitations; risks related to commercializing new products; unexpected or unfavorable new data; 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; risks associated with obtaining stockholder approval; having 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 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.

SIGNATURES

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.

ARENA PHARMACEUTICALS, INC.

Dated: May 15, 2012

By: /s/ Steven W. Spector
Steven W. Spector

Executive Vice President, General Counsel and

Secretary