ARENA PHARMACEUTICALS INC
Form 8-K
November 08, 2013

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): November 7, 2013

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.)**

6154 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., wholly owned subsidiaries, unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH. BELVIQ is the trade name for lorcaserin hydrochloride in the United States. While lorcaserin hydrochloride may in the future be marketed outside of the United States as BELVIQ or under a different trade name, we use BELVIQ in this report to refer to the finished drug product for lorcaserin hydrochloride or, depending on the context, lorcaserin hydrochloride or other solid state forms of lorcaserin.

Item 1.01 Entry into a Material Definitive Agreement.

On November 7, 2013, our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, Eisai Inc., and Eisai Inc. s parent company, Eisai Co., Ltd. (collectively with Eisai Inc., Eisai) entered into a Second Amended and Restated Marketing and Supply Agreement, or Second Amended Agreement, which expands Eisai s exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Eisai s commercialization rights are subject to applicable regulatory approval.

In July 2010, Arena GmbH and Eisai entered into the original Marketing and Supply Agreement, or Original Agreement, under which Arena GmbH granted Eisai Inc. exclusive commercialization rights for BELVIQ solely in the United States and its territories and possessions. In May 2012, Arena GmbH and Eisai Inc. amended and restated such agreement by entering into the Amended and Restated Marketing and Supply Agreement, or First Amended Agreement, which expanded Eisai Inc. s exclusive commercialization rights to include most of North and South America, including Canada, Mexico and Brazil. The Second Amended Agreement amends and restates the First Amended Agreement.

Upfront and Milestones

In connection with entering into the Second Amended Agreement, Arena GmbH will receive from Eisai an upfront payment of $60.0 million. This upfront payment is in addition to the $55.0 million Arena GmbH received in aggregate upfront payments in connection with entering into the Original Agreement and First Amended Agreement. Arena GmbH is also eligible to receive up to an aggregate of $176.5 million in regulatory and development milestone payments. These milestone payments include an aggregate of $53.5 million in such potential milestone payments that remained available for Arena GmbH to achieve under the First Amended Agreement and an aggregate of $123.0 million in additional potential milestone payments under the Second Amended Agreement.

Product Purchase Price Payments

As under the First Amended Agreement, Arena GmbH will manufacture BELVIQ at its facility in Switzerland, Eisai will purchase all of its requirements of BELVIQ from Arena GmbH, and Arena GmbH will sell BELVIQ to Eisai for commercialization in the United States and in the other territories in North and South America for a purchase price starting at 31.5% and 30.75%, respectively. With respect to the new territories added under the Second Amended Agreement, the purchase price starts at 27.5% in Europe, China and Japan, and at 30.75% in all of the other new territories under the Second Amended Agreement. All such purchase prices are a percentage of Eisai s net product sales. The purchase price will increase on a tiered basis in the United States and the other countries (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai s annual aggregate net product sales exceeding $750.0 million in all territories other than Europe, China and Japan. The purchase price will increase to 35% in Europe, China and Japan on the portion of Eisai s annual aggregate net product sales exceeding $500.0 million. Eisai s annual net product sales are subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country.

The Second Amended Agreement continues to include certain payments by Eisai if certain annual minimum sales requirements in Canada, Mexico and Brazil are not met during the first ten years after initial commercial sale in such territories.

Arena GmbH s eligibility to receive up to an aggregate of $1.19 billion in one-time purchase price adjustment payments and other payments will now be based on Eisai s annual net product sales in all of the territories under the Second Amended Agreement on an aggregate basis, with the first and last amounts payable, as they were under the First Amended Agreement, with annual net sales of $250.0 million and $2.5 billion, respectively. Of these payments, Eisai will pay Arena GmbH a total of $330.0 million for annual net sales of up to $1.0 billion.

Arena GmbH continues to be eligible to receive up to an additional $185.0 million in one-time purchase price adjustment payments based on Eisai s annual net product sales in non-US territories in North and South America, with the first and last amounts payable upon first achievement of annual net sales of $100.0 million and $1.0 billion in such territories, respectively. Under the Second Amended Agreement, Arena GmbH is now also eligible to receive up to an additional $185.0 million in one-time purchase price adjustment payments based on Eisai s annual net product sales in the territories outside of North and South America, with the first and last amounts payable upon first achievement of annual net sales of $100.0 million and $1.0 billion in such territories, respectively.

Development Payments

With respect to any post-approval development work for BELVIQ for weight management required by the US Food and Drug Administration, Arena GmbH and Eisai will continue to be responsible for 10% and 90%, respectively, of the expenses for such work other than the expenses of certain pediatric or adolescent studies, which Arena GmbH and Eisai will share equally. With respect to the rest of North and South America, Arena GmbH and Eisai will continue to be responsible for 10% and 90%, respectively, of the expenses for any pre- or post-approval development work with respect to BELVIQ for weight management required by a regulatory authority other than the expenses for stability testing, which Arena GmbH and Eisai will share equally.

With respect to the territories outside of North and South America, Arena GmbH and Eisai will each fund 50% of any required pre-approval development expenses related to BELVIQ for weight management, up to an aggregate of $50.0 million by each party for all territories outside of North and South America combined. Thereafter, Eisai will be responsible for 100% of the expenses for such work.

With respect to lorcaserin products other than BELVIQ for weight management, Arena GmbH and Eisai will equally fund the pre-approval development throughout the territories under the Second Amended Agreement. Arena GmbH and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation, a fixed-dose combination with phentermine, as well as exploring BELVIQ s impact on diabetes and cardiovascular outcomes.

With respect to any required post-approval development expenses related to BELVIQ for weight management for territories outside of North and South America, Arena GmbH and Eisai will each fund 50% of such expenses, up to an aggregate of $25.0 million by each party for all territories outside of North and South America combined. Thereafter, Arena GmbH and Eisai will be responsible for 10% and 90%, respectively, of the expenses for such work. With respect to any required post-approval development expenses related to lorcaserin products other than BELVIQ for weight management, Arena GmbH and Eisai will each fund 50% of such expenses, up to an aggregate of $50.0 million by each party for all such products combined. Thereafter, Arena GmbH and Eisai will be responsible for 10% and 90%, respectively, of the expenses for such work.

Certain Other Terms

Arena GmbH and Eisai have agreed to not commercialize outside of the Second Amended Agreement any weight management product in the territories under the Second Amended Agreement. The Second 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 Second Amended Agreement with respect to any country in the territory following the later of the expiration of all issued BELVIQ patents in such country and 12 years after the first commercial sale of BELVIQ in such country. Arena GmbH and Eisai each has the right to terminate the Second Amended Agreement early in certain circumstances in its entirety or with respect to the applicable country or product, 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 Second 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 BELVIQ in such country exceed sales of BELVIQ in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with BELVIQ. In addition, Arena GmbH can terminate the Second Amended Agreement early in its entirety or with respect to each country in the non-US territories in North and South America 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 losses resulting from certain third-party claims, including for (a) Eisai s negligence, willful misconduct or violation of law, but excluding product liability claims, (b) Eisai s breach of the Second Amended Agreement or related agreements, but excluding product liability claims, (c) certain uses or misuses of BELVIQ, (d) certain governmental investigations of Eisai related to BELVIQ, and (e) infringement relating to Eisai s use of certain trademarks, tag lines and logos related to BELVIQ. Arena GmbH will indemnify Eisai for losses resulting from certain third-party claims, including for (i) Arena GmbH s negligence, willful misconduct, failure to comply with law, breach of any agreement with a third party with respect to product development prior to the effective date of the original agreement with Eisai, but excluding product liability claims, (ii) Arena GmbH s negligence or willful misconduct with respect to certain uses or misuses of BELVIQ outside of the agreement, (iii) certain uses or misuses of BELVIQ after the term of the agreement, in any territory no longer under the agreement or with respect to any product after the termination of the agreement with respect to such product, (iv) Arena GmbH s negligence, willful misconduct or violation of law, but excluding product liability claims, (v) Arena GmbH s breach of the Second Amended Agreement or related agreements, but excluding product liability claims, (vi) certain infringement of intellectual rights of a third party, and (vii) infringement relating to Eisai s use of certain trademarks related to BELVIQ. In addition, Arena GmbH and Eisai will share equally in losses resulting from third-party product liability claims, except where one party s acts or omissions did not contribute to the events or circumstances leading to such product liability claim and the other party s actual willful misconduct, violation of law or breach of its obligations under the Second Amended Agreement or certain other agreements between Arena GmbH and Eisai were the sole and direct cause of the product liability claim.

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, regulatory review and approval, and potential of BELVIQ or lorcaserin; and the Second Amended Agreement, the significance of such agreement and related expectations and plans, including payments, product development (including potential indications and formulations), manufacture of BELVIQ, sale of finished product, registration and commercialization.

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For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena s 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 Second Amended Agreement and dependence on collaborators; the timing and receipt of payments and fees, if any, from collaborators; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ, including the impact of competition; our revenues will be based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to our guidance or previously reported results; the timing and outcome of regulatory review is uncertain, and BELVIQ may not be approved for marketing when expected or ever in combination with another drug, for another indication or using a different formulation or in any other territory for any indication; regulatory decisions in one territory may impact other regulatory decisions and our business prospects; government and commercial reimbursement and pricing decisions; the entry into or modification or termination of collaborative arrangements; unexpected or unfavorable new data; 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 us or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; data and other information related to any of our research and development may not meet regulatory requirements or otherwise be sufficient for further research and development, regulatory review or approval or continued marketing; our ability to obtain and defend patents; the timing, success and cost of our research and development; 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: November 8, 2013

Arena Pharmaceuticals, Inc.

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