ARENA PHARMACEUTICALS INC
Form 8-K
January 04, 2017

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): December 28, 2016

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, we, us and our refer to Arena Pharmaceuticals, Inc., and our wholly owned subsidiaries, unless the context otherwise provides. Lorcaserin has been approved in the United States, South Korea, Mexico and Brazil for weight management in a twice-a-day dosage formulation. The twice-a-day dosage formulation is being commercialized in the United States and South Korea under the brand name BELVIQ®, and is expected to be commercialized in Mexico under the brand name VENESPRI®. Lorcaserin has also been approved in the United States in a once-a-day dosage formulation, which is BELVIQ XR®. In this report, BELVIQ refers to each of the formulations of lorcaserin approved for weight management, unless the context otherwise indicates.

Item 1.01 Entry into a Material Definitive Agreement.

On December 28, 2016, our wholly owned subsidiary, 356 Royalty Inc. (356 Royalty), entered into a Transaction Agreement with Eisai Inc. and Eisai Inc. s parent company, Eisai Co., Ltd. (collectively with Eisai Inc., Eisai). Concurrently with the Transaction Agreement, on December 28, 2016, our wholly owned subsidiary, Arena Pharmaceuticals GmbH (Arena GmbH), entered into a Supply Agreement with Eisai.

Pursuant to the Transaction Agreement and the Supply Agreement, we have agreed to transfer to Eisai certain patents, regulatory approvals, samples, records, know-how related to BELVIQ, trademarks (including the trademarks BELVIQ, BELVIQ XR and VENESPRI), our agreements with distributors of BELVIQ in South Korea, Taiwan and Israel, and domain names related to BELVIQ.

The Transaction Agreement and the Supply Agreement replace the Second Amended and Restated Marketing and Supply Agreement (Second Amended Agreement), dated November 7, 2013, by and among Arena GmbH and Eisai, under which we granted Eisai exclusive commercialization rights for BELVIQ in all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel.

Transaction Agreement

Pursuant to the Transaction Agreement, 356 Royalty is granting Eisai an exclusive, royalty-bearing license, or transferring intellectual property, to develop, manufacture and commercialize lorcaserin in all countries and territories of the world (collectively, the Territory). In consideration for the rights granted to Eisai under the Transaction Agreement, Eisai has agreed to make tiered royalty payments to 356 Royalty on the net sales of lorcaserin in the Territory. The royalty rates range from 9.5% on annual global net sales less than or equal to $175 million, 13.5% on annual global net sales greater than $175 million but less than or equal to $500 million and 18.5% on annual global net sales greater than $500 million.

356 Royalty is eligible to receive up to $26 million in milestone payments under the Transaction Agreement, $25 million of which will be payable upon the achievement of a sales milestone, and $1 million of which will be payable upon the achievement of a regulatory milestone.

Eisai will be solely responsible for all costs and expenses in connection with the development of BELVIQ, and Arena GmbH will be relieved of its obligation under the Second Amended Agreement to pay for its share of development costs for BELVIQ, which could have exceeded $80 million over the next three years. Eisai will have the exclusive right and responsibility to plan and implement all research and development of BELVIQ at its own cost and expense, including conducting all regulatory activities and all clinical and development activities. Additionally, Eisai has agreed to (a) conduct all studies required by the U.S. Food and Drug Administration as a condition of obtaining and maintaining regulatory approval of BELVIQ in the United States, (b) continue the current study assessing whether BELVIQ reduces the incidence of major cardiovascular events, (c) continue the current study assessing whether BELVIQ reduces the incidence of conversion to Type 2 diabetes mellitus, and (d) use commercially reasonable efforts to develop and seek regulatory approval of BELVIQ in each of China, Japan and the European Union.

Eisai will be solely responsible, and have the exclusive rights, for commercializing BELVIQ in the Territory and will be responsible for manufacturing BELVIQ, except for any manufacturing to be conducted by Arena GmbH under the Supply Agreement. Eisai will be responsible for using commercially reasonable efforts to commercialize lorcaserin products in the United States, the European Union, China and Japan (the Major Markets) after regulatory approval in the applicable market.

356 Royalty and Eisai will each bear 50% of all expenses and losses arising from any product liability claim during a specified period after the date of the Transaction Agreement. Thereafter, 356 Royalty and Eisai will each bear 50% of all expenses and losses arising from any alleged defective manufacturing of BELVIQ by Arena GmbH under the Supply Agreement, and Eisai will be solely responsible for any expenses and losses associated with other product liability claims.

Eisai has agreed to certain standstill provisions, pursuant to which it Eisai is obligated to refrain from taking certain actions with respect to Arena s common stock during the term of the Transaction Agreement and for two years thereafter.

The Transaction Agreement will remain in effect until terminated by 356 Royalty or Eisai with respect to all countries in the Territory. 356 Royalty may terminate the Transaction Agreement with respect to a Major Market if Eisai permanently ceases development and commercialization of lorcaserin products in such Major Market, or in its entirety if Eisai permanently ceases development and commercialization of lorcaserin products in the Territory. 356 Royalty may also terminate the Transaction Agreement if Eisai challenges any patent controlled by 356 Royalty related to lorcaserin as of the effective date of the Transaction Agreement (licensed patents), if Eisai is debarred under the United States Federal Food, Drug, and Cosmetic Act, or if Eisai is in material breach of the standstill provisions. Eisai may terminate the Transaction Agreement if as a result of its change of control, it would be in breach of certain competition restrictions.

In the event the Transaction Agreement is terminated by 356 Royalty due to Eisai s failure to develop and commercialize lorcaserin products, Eisai s challenging of any of the licensed patents or Eisai s debarment or material breach of the standstill provisions, or by Eisai after a change of control that would result in Eisai being in breach of certain competition restrictions, Eisai will grant Arena an exclusive, royalty-free license to certain patent rights and know-how necessary or useful for the development and commercialization of lorcaserin products in the Territory, re-assign the assets purchased by Eisai under the Transaction Agreement and Supply Agreement, and provide certain other transition assistance.

Supply Agreement

Under the Supply Agreement, Arena GmbH has agreed to manufacture and supply, and Eisai has agreed to purchase, all of Eisai s requirements (or specified minimum quantities if such quantities are greater than Eisai s requirements), subject to certain exceptions, for BELVIQ and BELVIQ XR for the development and commercial use of such products in the Territory for an initial 24-month period, which initial period may be extended by Eisai for an additional six months upon payment of an extension fee of CHF 2 million. Eisai will pay Arena GmbH agreed upon prices to deliver finished drug product during this time. Additionally, Eisai has agreed to make up to CHF 13 million in payments to Arena GmbH to support the maintenance of Arena GmbH s manufacturing facility in Switzerland during the initial 24-month period supply period, and up to CHF 6 million during the six-month extension period, if any.

Pursuant to the Supply Agreement, Arena GmbH will transfer to Eisai all know-how and materials necessary for Eisai to manufacture BELVIQ at the facility in accordance with Arena GmbH s manufacturing processes used at the effective date of the Supply Agreement or 24 months prior.

Pursuant to the Supply Agreement, Arena GmbH will grant to Eisai during the term of the Transaction Agreement an exclusive license under Arena GmbH s rights in the know-how and records controlled by Arena GmbH used for the development, manufacture or commercialization of BELVIQ in the Territory in accordance with the Supply Agreement.

On the effective date of the Supply Agreement, Eisai will purchase all of Arena GmbH s inventory of the precursor materials for manufacturing BELVIQ then in Arena GmbH s possession. In exchange for these materials Eisai will make a one-time payment to Arena GmbH of $10 million (USD).

Absent early termination, the Supply Agreement will remain in effect until (a) the last day of the initial 24-month supply period, or the last day of the six-month extension period (if any), or up to two weeks thereafter if so requested by Eisai, or (b) in the event of an acquisition of Arena or Arena GmbH by a third party, or of an assignment of the

Supply Agreement by Arena GmbH to a third party, five years after the effective date of the Supply Agreement. After the initial 24-month period of the Supply Agreement, either Arena GmbH or Eisai may terminate the Supply Agreement upon the other party s material breach that remains uncured 60 days after receiving written notice thereof. The Supply Agreement will also terminate automatically upon termination of the Transaction Agreement.

Forward-Looking Statements

Statements in this report on Form 8-K that are not statements of historical fact are forward-looking statements, which involve a number of risks and uncertainties. Such forward-looking statements include, without limitation, payments to be made or received pursuant to the Transaction Agreement or the Supply Agreement and activities to be performed under such agreements. Words such as believe, anticipate, plan, expect, intend, will, may, goal, poten expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. 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, risks related to: the implementation and continuation of the Transaction Agreement and the Supply Agreement; dependence on counterparty performance; 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; government and commercial reimbursement and pricing decisions; unexpected or unfavorable new data; and Arena s or Eisai s ability to defend patent rights. Additional factors that could cause actual results to differ materially from those stated or implied by Arena s 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 this report on 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 4, 2017

Arena Pharmaceuticals, Inc.

By: /s/ Amit Munshi
Amit Munshi
President and Chief Executive Officer