

ARENA PHARMACEUTICALS INC

Form 8-K

January 08, 2018

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 8, 2018

Arena Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction

000-31161

23-2908305
(IRS Employer

of Incorporation)

(Commission File Number) Identification No.)

6154 Nancy Ridge Drive,

San Diego, CA
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 453-7200

Not Applicable

(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 (see General Instructions A.2. below):

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

In this report, “Arena Pharmaceuticals,” “Arena,” “Company,” “we,” “us” and “our” refer to Arena Pharmaceuticals, Inc., and/or one or more of our wholly owned subsidiaries, unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc.

Item 7.01 Regulation FD Disclosure.

On January 8, 2018, Axovant Sciences GmbH reported topline results of a pilot Phase 2 study for the investigational drug nelotanserin. Nelotanserin was discovered by Arena and is the subject of a Development, Marketing and Supply Agreement between Arena and Axovant. Additional information regarding the study results is provided in Axovant’s press release of the same date titled, in part, “Axovant Announces... Positive Trends in Efficacy Seen in Pilot Phase 2 Nelotanserin Study.”

About Nelotanserin

Nelotanserin, an orally available potent and selective inverse agonist of the 5-HT_{2A} receptor, is an investigational drug candidate. The 5-HT_{2A} receptor has been implicated in the pathophysiology underlying psychosis. Nelotanserin was discovered by Arena.

Nelotanserin development

Under our Development, Marketing and Supply Agreement, Axovant is currently conducting phase 2 studies for different potential indications. On January 8, 2018, Axovant announced results from a pilot phase 2, multi-center, double-blind, placebo-controlled crossover study evaluating nelotanserin in patients with dementia with Lewy bodies (DLB) and Parkinson’s disease dementia (PDD) suffering from visual hallucinations. Axovant is also conducting a phase 2, multi-center, double-blind, placebo-controlled study evaluating nelotanserin in patients with DLB and PDD experiencing rapid eye movement (REM) sleep behavior disorder (RBD). We expect Axovant will seek to develop nelotanserin to address multiple aspects of neurological conditions. Axovant will be responsible for funding the development and commercialization of nelotanserin.

Nelotanserin collaboration

In May 2015, we entered into a Development, Marketing and Supply Agreement with Roivant Sciences Ltd., or Roivant, for nelotanserin. Roivant subsequently assigned all of its rights to develop and commercialize nelotanserin to its subsidiary, Axovant. Under our collaboration, Axovant has exclusive worldwide rights to develop and commercialize nelotanserin, and Arena will be responsible for manufacturing nelotanserin to sell to Axovant. We are eligible to receive \$41.5 million in regulatory and development milestone payments. We are also eligible to receive 15% of net sales of nelotanserin in exchange for the manufacture and supply of finished commercial drug product, and up to a total of \$60.0 million in one-time purchase price adjustment payments tied to certain commercial sales milestones.

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, statements about the expected development and activities under our collaboration agreement with Axovant. Words such as “expect,” “will,” and similar 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: topline data may not accurately reflect the complete results of a study or trial; nonclinical and clinical data are voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Axovant or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; unexpected or unfavorable new data; clinical trials and other studies may not proceed at the time or in the manner expected or at all; intellectual property rights; relying on collaborative arrangements, and the entry into or modification or termination of collaborative arrangements; regulatory approval and commercialization is uncertain; competition; and our collaborator’s financial and other resources. 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.

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 thereunto duly authorized.

Date: January 8, 2018 Arena Pharmaceuticals, Inc.

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