ARENA PHARMACEUTICALS INC
Form 8-K
January 07, 2019
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 7, 2019

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.)
6154 Nancy Ridge Drive, San Diego, CA		92121
(Address of Principal Executive Offices)		(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):

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.

In this report, “Arena Pharmaceuticals,” “Arena,” “Company,” “we,” “us” and “our” refer to Arena Pharmaceuticals, Inc., and/ 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 2.02 Results of Operations and Financial Condition.

Commencing on January 7, 2019, we expect to disclose the following information in discussions to be held in connection with the Annual J.P. Morgan Healthcare Conference: As of December 31, 2018, the Company had approximately $528 million of cash, cash equivalents, and investments. See additional information in the presentation furnished as an exhibit to Item 7.01.

Item 7.01 Regulation FD Disclosure.

Included as Exhibit 99.1 to this Form 8-K is a presentation titled “Arena Pharmaceuticals Corporate Presentation,” dated January 2019, which is incorporated herein by reference. We intend to utilize this presentation and its contents in various meetings with securities analysts, investors and others in connection with the Annual J.P. Morgan Healthcare Conference, commencing on January 7, 2019.

The information contained in Exhibit 99.1 hereto is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Long-Term Data from the Open-Label Extension of the Phase 2 OASIS Trial Evaluating Etrasimod for Treatment of Ulcerative Colitis

On January 7, 2019, we announced positive data from the open-label extension (OLE) of the Phase 2 OASIS trial of our investigational drug candidate etrasimod, a next-generation, oral, selective sphingosine 1 phosphate (S1P) receptor modulator in development for the treatment of moderate to severely active ulcerative colitis (UC). Overall, etrasimod demonstrated durable, long-term clinical remission and was generally safe and well tolerated in this trial.

Open-Label Extension of Phase 2 OASIS Trial Design

This was a 34-week open-label extension evaluating the long-term safety, tolerability and efficacy of etrasimod in 118 subjects (84% of OASIS study completers) who completed the 12-week Phase 2 OASIS randomized, placebo-controlled trial. Of the 118 subjects, 105 received only 2 mg etrasimod during the OLE study regardless of previous study treatment. Key efficacy measurements included clinical response, clinical remission, and endoscopic improvement at end of treatment (46 weeks).

Key Efficacy Measurements

Of the subjects who completed 2 mg etrasimod treatment during the OLE study (n=84), 79% achieved clinical response, 39% achieved clinical remission, and 51% had endoscopic improvement at the end of the OLE study.

For OLE study completers who received 2 mg etrasimod in the original Phase 2 OASIS trial (n=22), 82% experienced clinical response, 50% were in clinical remission, and 55% had endoscopic improvement at the end of the OLE study.

Among subjects achieving clinical response or clinical remission on 2 mg etrasimod at 12 weeks in OASIS, sustained treatment effect over 46 weeks was observed, with 93% experiencing sustained clinical response and 75%

experiencing sustained clinical remission at both 12 and 46 weeks.

Key Safety Measurements

Etrasimod demonstrated a favorable long-term safety profile; adverse events in the OLE study were generally mild to moderate in severity and no new safety findings were noted. Impact on heart rate and atrioventricular (AV) conduction was minimal throughout the study with no discontinuations from study related to bradycardia or AV block.

The Company plans to present full study results at future medical congresses.

About Etrasimod

Etrasimod (APD334), is a next generation, oral, selective sphingosine 1 phosphate (S1P) receptor modulator, discovered by Arena, designed to provide systemic and local cell modulation by selectively targeting S1P receptor subtypes 1, 4 and 5. Etrasimod has therapeutic potential in immune and inflammatory-mediated diseases such as ulcerative colitis, Crohn's disease, primary biliary cholangitis (PBC) and atopic dermatitis. S1P receptors have been demonstrated to be involved in the modulation of several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood. By isolating subpopulations of lymphocytes in lymph nodes, fewer immune cells are available in the circulating blood to effect tissue damage.

Etrasimod is an investigational compound that is not approved for any use in any country.

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be identified by introductory words such "evaluating," "in development for," "designed to," "potential," or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements regarding the intention and plan to progress etrasimod's development; and etrasimod's potential, including to have therapeutic potential in a broad range of immune and inflammatory-mediated diseases such as ulcerative colitis, Crohn's disease, PBC, and atopic dermatitis, and to modulate several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood. 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, without limitation, the following: the announced data are based on an interim analysis of certain key measurements, and such interim data or analysis may change following a more comprehensive review of the data, and such interim data or analysis may not accurately reflect the final results of the study; the reported-on trial was not a placebo-controlled study; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; 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 Arena or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; the timing and outcome of research, development and regulatory review is uncertain; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling patients in our ongoing and intended clinical trials is competitive and challenging; unexpected or unfavorable new data; risks related to developing and commercializing drugs; risks related to relying on partners and other third parties; Arena's and third parties' intellectual property rights; 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 (SEC), including but not limited to our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. These forward-looking statements represent our judgment as of the time of this release. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Description

Number	
99.1	Arena Pharmaceuticals Corporate Presentation, dated January 2019

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 7, 2019 Arena Pharmaceuticals, Inc.

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