ARENA PHARMACEUTICALS INC
Form 8-K
March 19, 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): March 19, 2018

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 7.01 Regulation FD Disclosure.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical data results discussed in Item 8.01 below. We intend to present the slides during a conference call and live webcast with the investment community on March 19, 2018, at 4:30 p.m. EDT.

The information contained in this Item 7.01, including 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.

Topline Phase 2 Results for Etrasimod

On March 19, 2018, we announced positive topline Phase 2 results from the OASIS trial for etrasimod, an investigational, once-daily, orally administered, selective sphingosine 1-phosphate (S1P) receptor modulator in development for the treatment of ulcerative colitis (UC). Patients receiving a 2 mg dose of etrasimod achieved statistically significant improvements versus placebo in the primary, all secondary, and clinical remission endpoints.

Relative to placebo, there was a statistically significant ($p = 0.009$) 0.99 point improvement in a 3-component (stool frequency, rectal bleeding and findings on endoscopy) Mayo Clinic Score (ranging from 0 to 9) with etrasimod 2 mg at week 12. In the 1 mg group, there was a 0.43 point improvement in 3-component Mayo Clinic Score at week 12 relative to placebo, which was not statistically significant ($p = 0.146$). Significantly more patients in the etrasimod 2 mg group achieved endoscopic improvement compared with placebo (41.8% vs. 17.8%, $p = 0.003$).

The proportion of patients achieving clinical remission, defined by the 3-component Mayo Clinic Score, was 33.0% in the etrasimod 2 mg group compared to 8.1% for the placebo group ($p < 0.001$). Remission as defined by the 4-component Total Mayo Clinic Score was 24.5% and 6.0% for etrasimod 2 mg and placebo, respectively ($p = 0.004$).

Etrasimod was well tolerated and there were fewer patients with serious adverse events (SAEs) compared to placebo (0% in 2 mg, 5.8% in 1 mg and 11.1% in placebo). Impact on heart rate and atrioventricular (AV) conduction was low throughout the study with no discontinuations from study related to bradycardia or AV block. There were no increases in liver function tests compared to placebo and no reports of macular edema or pulmonary function test abnormalities. We plan to present full study results at future medical congresses. We intend to initiate a Phase 3 program for etrasimod in ulcerative colitis.

About OASIS

OASIS was a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to assess safety and efficacy of two orally administered doses (1 mg and 2 mg) of etrasimod in patients with ulcerative colitis (UC) across 71 sites in 16 countries. The OASIS trial randomized 156 patients, with moderate to severe UC (3-component Mayo Clinic Score of 4-9 with an endoscopic subscore ≥ 2 and a rectal bleeding score ≥ 1). The pre-specified statistical analysis plan applied one-sided testing, in which conventional statistical significance is achieved at p-values < 0.025.

About Etrasimod

Etrasimod (APD334), is an oral, once-daily, next generation, selective sphingosine 1-phosphate (S1P) receptor modulator, discovered by us, designed to provide systemic and local cell modulation by targeting S1P receptor subtypes 1, 4 and 5, while avoiding subtypes 2 and 3. Etrasimod is believed to exhibit potentially best-in-class pharmacokinetics and pharmacodynamics with rapid onset of action and rapid recovery of T lymphocytes. Selective binding with S1P receptor subtype 1 is believed to inhibit a specific subset of activated lymphocytes from migrating to sites of inflammation. The result is a reduction of circulating T and B lymphocytes that leads to anti-inflammatory activity while immune surveillance is maintained. The receptor subtypes 4 and 5 exhibit similar activity on additional proliferating immune cell types. Optimized pharmacology and pharmacokinetics may allow improved clinical utility across a broad range of immune and inflammatory conditions.

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

Item 9.01 Financial Statements and Exhibits. (d) Exhibits.

Exhibit

No.	Description
99.1	Slide presentation dated March 19, 2018, titled "Etrasimod Phase 2 in Ulcerative Colitis OASIS Clinical Trial Results."

Forward-Looking Statements

Statements in this report on Form 8-K that are not statements of historical fact are forward-looking statements that involve a number of risks and uncertainties. Such statements include, without limitation, statements regarding etrasimod, its potential to be best-in-class, and its potential to allow improved clinical utility across a broad range of immune and inflammatory conditions; plans for etrasimod's Phase 3 program; publication plans; and other statements that are not historical facts, including statements that may include the words "plans," "intend," "designed to," "potentially," "believed to," and "may". 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 the following: the topline data is based on preliminary analysis of key data, and such data or analysis may change following a more comprehensive review of the data, and such topline data may not accurately reflect the complete results of a particular study or trial; 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 us 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; our and third parties' intellectual property rights; satisfactory resolution of litigation or other disagreements with others; and those factors disclosed in our filings with the Securities and Exchange Commission (SEC), including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 14, 2018. 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: March 19, 2018 Arena Pharmaceuticals, Inc.

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