MOMENTA PHARMACEUTICALS INC
Form 8-K
November 29, 2016

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 29, 2016**

Momenta Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-50797**	**04-3561634**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

675 West Kendall Street, Cambridge, MA	**02142**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(617) 491-9700**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 29, 2016, Momenta Pharmaceuticals, Inc. (the Company) announced that the confirmatory Phase 3 clinical study of M923, a biosimilar HUMIRA® (adalimumab) candidate, in patients with moderate-to-severe chronic plaque psoriasis, met its primary endpoint. The proportion of subjects who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index (PASI-75) following 16 weeks of treatment, was equivalent with M923 or HUMIRA. The estimated difference in responders was well within the pre-specified confidence interval, confirming equivalence.

Equivalence was also achieved for all secondary efficacy endpoints, including the achievement of PASI-50, PASI-90, proportion achieving clear or near-clear skin, and change from baseline in absolute PASI score. Adverse events were comparable in terms of type, frequency, and severity, and were consistent with the published safety data for HUMIRA.

The study was a confirmatory, randomized, double-blind, multicenter study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis. Patients received up to 48 weeks treatment with M923, HUMIRA, or HUMIRA alternating with M923. The full dataset from this study will be presented at future conferences and in future publications.

M923 was developed pursuant to a Development, License and Option Agreement, dated as of December 22, 2011 (the Agreement), by and between the Company and Baxalta US Inc., Baxalta GmbH and Baxalta Incorporated (collectively, Baxalta). As previously reported, in September 2016, the Company received written notice from Baxalta that Baxalta had exercised its right to terminate for its convenience the Agreement.

Forward-Looking Statements

Statements in this report regarding management s future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements about expectations about the analysis, clinical significance and future presentation of the full dataset from the Phase 3 study. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including the Company s ability to complete the analysis of, and related reports on, the Phase 3 study full data set, as well as those factors set forth in the section Risk Factors in the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company s actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this report as of this date and assumes no obligations to update the information included in this report or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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.

MOMENTA PHARMACEUTICALS, INC.

Date: November 29, 2016

By: /s/ Craig A. Wheeler
Craig A. Wheeler
President and Chief Executive Officer