MOMENTA PHARMACEUTICALS INC
Form 8-K
January 06, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 6, 2017**

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in 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)

(617) 491-9700

(Registrant s telephone number, including area code)

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 Instruction A.2. below):

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 2.02 Results of Operations and Financial Condition.

On January 6, 2017, Momenta Pharmaceuticals, Inc. (the Company) announced certain preliminary financial results for the fourth quarter ended December 31, 2016. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Information.

On January 6, 2017, the Company provided a year-end 2016 corporate update, which included the following items:

M834: a proposed biosimilar of ORENCIA® (abatacept) being developed in collaboration with Mylan

- On December 22, 2016, the U.S. Patent and Trademark Office s Patent Trial and Appeal Board issued its decision upholding the validity of U.S. Patent No. 8,476,239, related to Bristol Myers Squibb s ORENCIA (abatacept) product following the Company s Inter Partes Review challenging this patent. The Company is considering its options for appeal to the U.S. Court of Appeals for the Federal Circuit.

M710: an early-stage biosimilar candidate being developed in collaboration with Mylan

- In December 2016, Momenta received a $35.0 million milestone payment from Mylan to be applied toward the funding of Mylan s 50% share of collaboration expenses.

Glatopa: First FDA-approved, substitutable generic daily COPAXONE® 20 mg for multiple sclerosis

- Glatopa 20 mg remains the sole generic 20 mg product on the market with approximately 40% penetration of the once-daily 20 mg/mL U.S. glatiramer acetate market.

- The Company expects that in the fourth quarter of 2016 its share of profit on Sandoz s sales of Glatopa 20 mg will be reduced by approximately $3.5 million to reimburse Sandoz for the Company s share of Glatopa-related legal expenses.

- The Abbreviated New Drug Application (ANDA) submitted by Sandoz for a three-times-a-week generic COPAXONE® 40 mg (glatiramer acetate injection) is under U.S. Food and Drug Administration (FDA) review. A tentative approval, if any, for Glatopa 40 mg could be granted at any time and a final approval could be granted following the expiration of COPAXONE 40 mg regulatory exclusivity on January 28, 2017.

M281: Fully human monoclonal antibody (mAb) targeting the neonatal Fc receptor (FcRn), currently in an ongoing Phase 1 study

- The Company has successfully completed five cohorts in the Phase 1 single ascending dose (SAD) study in healthy volunteers. In the SAD portion of the study a single dose of 30 mg/kg achieved up to 80% reduction of circulating IgG antibodies. M281 was well-tolerated and no serious adverse events were observed.

- The Company plans to report the full data from the single and multiple ascending dose portions of the study in the second half of 2017.

Item 9.01. **Financial Statements and Exhibits.**

(d) **Exhibits.**

Exhibit No.	Description
99.1	Press Release dated January 6, 2017

Forward-Looking Statements

Statements in this Current Report on Form 8-K 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 timing of patent litigation and other patent-related proceedings and decisions and available options related to such litigation and proceedings; expectations regarding the reduction of the Company s share of profit on Sandoz s sales of Glatopa 20 mg in the fourth quarter of 2016; expected timing of regulatory approval of the ANDA submitted by Sandoz for a three-times-a-week generic COPAXONE® 40 mg, and whether such ANDA will be approved at all; and expected timing of clinical trials and the availability and announcement of clinical data. Forward- looking statements may be identified by words such as believe, continue, expect, consider, could, plan, possible, potential, will and other similar words or e negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including those referred to under 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 important 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 Current Report on Form 8-K as of today s date and assumes no obligations to update the information included in this Current Report or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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 hereunto duly authorized.

MOMENTA PHARMACEUTICALS, INC.

Date: January 6, 2017

By: /s/ Scott M. Storer
Scott M. Storer
Senior Vice President, Chief Financial Officer