MOMENTA PHARMACEUTICALS INC
Form 8-K
January 08, 2016

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 8, 2016**

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 1.01 Entry into a Material Definitive Agreement

On January 8, 2016, Momenta Pharmaceuticals, Inc. (the Company) and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (Mylan), entered into a collaboration agreement (the Collaboration Agreement) pursuant to which the Company and Mylan will collaborate exclusively, on a world-wide basis, to develop, manufacture and commercialize six of the Company s biosimilar candidates, including M834, the Company s biosimilar ORENCIA® (abatacept) candidate. The Collaboration Agreement will be effective upon approval or the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

Under the terms of the Collaboration Agreement, Mylan has agreed to pay the Company a non-refundable upfront payment of $45 million. In addition, the Company and Mylan will share equally costs (including development, manufacturing, commercialization and certain legal expenses) and profits (losses), with Mylan funding its share of collaboration expenses incurred by the Company, in part, through up to six contingent early development milestone payments, totaling up to $200 million across the six product candidates.

For each product candidate other than M834, at a specified stage of early development, the Company and Mylan will each decide, based on the product candidate s development progress and commercial considerations, whether to continue the development, manufacture and commercialization of such product candidate under the collaboration or to terminate the collaboration with respect to such product candidate.

Under the Collaboration Agreement, the Company has granted Mylan an exclusive license under the Company s intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan has granted the Company a co-exclusive license under Mylan s intellectual property rights for the Company to perform its development and manufacturing activities under the product work plans agreed by the parties, and to perform commercialization activities for such product candidates if the Company exercises its co-commercialization option described below. The Company and Mylan will form a joint steering committee (JSC), consisting of an equal number of members from the Company and Mylan, to oversee and manage the development, manufacture and commercialization of product candidates under the collaboration. Unless otherwise determined by the JSC, it is anticipated that, in collaboration with the other party, (a) the Company will be primarily responsible for non-clinical development activities and initial clinical development activities for product candidates; additional (pivotal or phase 3 equivalent) clinical development activities for M834; and regulatory activities for product candidates in the United States through regulatory approval; and (b) Mylan will be primarily responsible for additional (pivotal or phase 3 equivalent) clinical development activities for product candidates other than M834; regulatory activities for product candidates outside the United States; and regulatory activities for products in the United States after regulatory approval. Mylan will commercialize any approved products, with the Company having an option to co-commercialize in a supporting commercial role, any approved products in the United States. The JSC will allocate responsibilities for other activities under the collaboration.

The term of the collaboration will continue throughout the development and commercialization of the product candidates, on a product-by-product and country-by-country basis, until development and commercialization by or on behalf of the Company and Mylan pursuant to the Collaboration Agreement has ceased for a continuous period of two years for a given product candidate in a given country, unless earlier terminated by either party pursuant to the terms of the Collaboration Agreement.

The Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. If a termination occurs, the licenses granted to the

non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that continues the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

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: January 8, 2016

By: /s/ Bruce A. Leicher

Bruce A. Leicher
Senior Vice President, General Counsel and Secretary