MOMENTA PHARMACEUTICALS INC
Form 8-K
January 05, 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 5, 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 1.01 Entry into a Material Definitive Agreement

On January 5, 2017, Momenta Pharmaceuticals, Inc. (the Company) and CSL Behring Recombinant Facility AG (CSL), a wholly-owned indirect subsidiary of CSL Limited, entered into a License and Option agreement (the Agreement) pursuant to which the Company has granted CSL an exclusive worldwide license to research, develop, and commercialize the Company s M230 pre-clinical product candidate, an Fc multimer protein that is a selective immunomodulator of the Fc receptor. The Agreement also provides, on an exclusive basis, for the Company and CSL to conduct research on other Fc multimer proteins, and provides CSL the right to develop and commercialize these additional research products globally. The Agreement will be effective upon approval or the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended (the Effective Date).

Pursuant to the Agreement, CSL has agreed to pay the Company a non-refundable upfront payment of $50 million. For the development and commercialization of M230, the Company is eligible to receive up to $550 million in contingent clinical, regulatory and sales milestone payments, and additional negotiated milestone payments for a named research stage product should that enter development. The Company is also entitled to sales-based royalty payments in percentages ranging from a mid-single digit to low-double digits for M230 and a named research stage product should that enter development and be commercialized, and royalties and development milestone payments to be negotiated for any other products developed under the Agreement. Sales milestones are based on aggregated sales across M230 and any other products. The Company also has the option to participate in a cost-and-profit sharing arrangement, under which the Company would fund 50 percent of global research, development and commercialization costs for all products developed pursuant to the Agreement (the Co-Funded Products) in exchange for either a 50 percent share of U.S. profits or 30 percent share of U.S. profits, determined by the stage of development at which the Company makes such election. For Co-Funded Products, royalties remain payable for territories outside of the United States and milestone payments are reduced. The Company also has the right to opt-out of such arrangement at its sole discretion, which would result in milestone payments and royalties reverting to their pre-arrangement amounts. The Company also has the option to participate in the promotion of Co-Funded Products in the United States, subject to a co-promotion agreement to be negotiated with CSL.

Under the Agreement, the Company has granted CSL an exclusive license under the Company s intellectual property to research, develop, manufacture and commercialize product candidates for all therapeutic indications. CSL has granted the Company a non-exclusive, royalty-free license under CSL s intellectual property for the Company s research and development activities pursuant to the Agreement and its commercialization activities under any co-promotion agreement with CSL.

The Company and CSL will form a joint steering committee (JSC), consisting of an equal number of members from the Company and CSL, to facilitate the research, development, and commercialization of product candidates.

Unless earlier terminated, the term of the Agreement commences on the Effective Date and continues until the later of (i) the expiration of all payment obligations with respect to products under the Agreement, (ii) the Company is no longer co-funding development or commercialization of any products and (iii) the Company and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the Agreement. Either party may terminate the Agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product or country-by-country basis for material breaches, or (iii) due to the other party s bankruptcy. Upon termination of the Agreement, subject to certain exceptions, the licenses granted under the Agreement terminate. In addition, dependent

upon the circumstances under which the Agreement is terminated, the Company or CSL has the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

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 5, 2017

By: /s/ Bruce A. Leicher
Bruce A. Leicher
Senior Vice President, General Counsel and Secretary