MOMENTA PHARMACEUTICALS INC
Form 8-K
September 27, 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): September 27, 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 1.02 Termination of a Material Definitive Agreement.

On September 27, 2016, Momenta Pharmaceuticals, Inc. (the "Company") received a written notice from Baxalta US Inc., Baxalta GmbH and Baxalta Incorporated (collectively, "Baxalta") stating that Baxalta has exercised its right to terminate for its convenience (the "Termination") the Development, License and Option Agreement, by and between the Company and Baxalta, dated as of December 22, 2011 (the "Agreement"), pursuant to which the Company and Baxalta agreed to collaborate, on a world-wide basis, on the development and commercialization of M923, the Company's biosimilar HUMIRA® (adalimumab) candidate. On June 3, 2016, Baxalta Incorporated and Shire plc ("Shire") announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated, of which Baxalta US Inc. and Baxalta GmbH are wholly-owned subsidiaries, is a wholly-owned subsidiary of Shire.

Pursuant to the terms of the Agreement, which terms have been previously disclosed in the Company's filings with the Securities and Exchange Commission (the "Commission"), including in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, each party granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. Baxalta is responsible for clinical development, manufacturing and commercialization activities for M923. Costs, including development costs, payments to third parties for intellectual property licenses, and expenses for legal proceedings are borne by the parties in varying proportions, depending on the type of expense and the stage of development. Under the terms of the Agreement, the Company received an initial cash payment of $33.0 million, a $7.0 million license payment for achieving pre-defined "minimum development criteria" for M834, the Company's biosimilar ORENCIA® (abatacept) candidate, and $12.0 million in technical and development milestone payments in connection with the UK Medicines and Healthcare Products Regulatory Agency's acceptance of Baxalta's clinical trial application to initiate a pharmacokinetic clinical trial for M923. Under the terms of the Agreement, if M923 is successfully developed and launched, Baxalta will be required to pay to the Company royalties on net sales of licensed products worldwide, with a base royalty rate in the high single digits with the potential for significant tiered increases based on the number of competitors, the interchangeability of the product, and the sales tier for the product. The maximum royalty with all potential increases would be slightly more than double the base royalty.

Under the terms of the Agreement, the effective date of the Termination is twelve months from the date of receipt of the Termination notice, as more particularly set forth in the Agreement (the "Effective Date"). As of the Effective Date, (i) Baxalta is obligated to transfer to the Company all ongoing regulatory, development, manufacturing and commercialization activities and related records for M923 and, at the Company's request, assign to the Company any third party agreements reasonably necessary for development, manufacture, and commercialization of M923, (ii) the licenses granted pursuant to the Agreement by the Company to Baxalta under the Company's intellectual property rights relating to M923 will terminate, the licenses granted pursuant to the Agreement by Baxalta to the Company under Baxalta's intellectual property rights relating to M923 will survive, and Baxalta is obligated to grant to the Company additional licenses under Baxalta's intellectual property rights relating to M923 existing as of the Effective Date, and (iii) the Company is obligated to pay to Baxalta a royalty of 5% of net sales, as such term is defined in the Agreement, until Baxalta's development expenses and commercialization costs, as such terms are defined in the Agreement, occurring through the Effective Date are reimbursed. Prior to the Effective Date, Baxalta is obligated to continue to perform development and manufacturing activities for M923, which is currently in a pivotal clinical trial from which data is expected to be reported in 2016.

The foregoing description of the Agreement is not complete and is qualified in its entirety by reference to the Agreement, a copy of which was filed with the Commission as Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify forward-looking statements by the use of forward-looking terminology such as “expect,” “will,” and other similar words or expressions, or the negative of these words or similar words or expressions. These forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company’s control. Statements in this Current Report on Form 8-K regarding the Company that are forward-looking, including statements regarding the transfer of regulatory, development, manufacturing and commercialization activities and related records for M923, the assignment of third party agreements, the grant of licenses, the payment of a royalty on net sales, Baxalta’s continuing to perform development and manufacturing activities for M923, and the timing of availability of clinical trial results, are based on management’s estimates, assumptions and projections, and are subject to significant uncertainties and other factors, many of which are beyond the Company’s control. Important factors that may cause actual results and other future events to differ materially from current expectations include, among other things, those listed under “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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: September 27, 2016 By: /s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer
(Principal Financial Officer)