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): **December 6, 2018**

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.)

301 Binney 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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

Momenta Pharmaceuticals, Inc. ("we" or "our") is providing the following business update.

The Company

We are a biotechnology company with a validated scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases.

Novel Therapeutics — Our Approach to Autoimmune Diseases

Many autoimmune diseases are characterized by the formation of autoantibodies that bind self-antigens to form immune complexes. These immune complexes can recruit and activate immune cells leading to tissue inflammation and damage. However, few therapeutic agents exist that interfere directly with these autoantibodies or immune complex-immune cell activation processes. The most commonly used treatments for autoantibody-driven disease are systemic immunosuppressants, which do not specifically target disease pathogenesis and which carry significant safety risks such as opportunistic infection and cancer. In addition to these treatments, intravenous immunoglobulin, or IVIg, a therapeutic drug product that contains pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma may be used to treat several inflammatory diseases, including idiopathic thrombocytopenic purpura, or ITP, chronic inflammatory demyelinating polyneuropathy, and multifocal motor neuropathy.

We are developing therapeutics for autoimmune diseases with a focus on rare immune-mediated disorders. There are approximately 45 rare autoimmune disorders driven by autoantibodies, and we estimate there are one to two million patients in the United States with these rare disorders. Initially we have applied our complex systems analysis and biological protein engineering platforms to develop an improved IVIg. We utilized our proprietary sialylation technology, a method to add sialic acid to protein, to create M254, a high potency alternative to IVIg that we believe improves upon the limitations of that therapeutic approach. By gaining a deeper understanding of IVIg and immune complex driven autoimmune diseases, we have designed two novel recombinant therapeutic candidates, M281 and M230, to leverage what we believe are key biologies associated with autoimmune diseases. The discovery of these candidates is based on our analysis of the role of the Fc region of IgG autoantibodies in maintaining persistence in circulation and in mediating tissue damage and inflammation in rare autoimmune diseases. The design of these agents is based on our expertise in biological protein engineering and proprietary Fc multimerization technology. We believe our novel product candidates could be capable of treating a large number of immune-mediated disorders driven by autoantibodies, immune complexes, and Fc receptor biology.

M281 — Anti-FcRn Product Candidate

We plan to commence a Phase 2 proof-of-concept clinical trial for M281 in generalized myasthenia gravis, or gMG, in the fourth quarter of 2018 and a Phase 2 open-label extension clinical trial in early 2019. We estimate that there are approximately 65,000 patients in the United States with myasthenia gravis.

We also plan to commence a Phase 2 proof-of-concept clinical trial for M281 in hemolytic disease of the fetus and newborn in the fourth quarter of 2018. We estimate there are approximately 10,000 to 20,000 patients in the United States with maternal fetal disorders.

M254 — hsIVIg Product Candidate

For M254, we plan to commence a Phase 1/2 proof-of-concept clinical trial in ITP in early 2019, pending regulatory feedback. We estimate the market for IVIg products to be more than $8 billion in 2018 and expect the market to grow by six to eight percent per year through 2022.

Late Stage Biosimilar Product Candidates

M923—Biosimilar HUMIRA® (adalimumab) Product Candidate

HUMIRA is a monoclonal antibody that can bind to a substance in the body known as tumor necrosis factor, or TNF, thereby inhibiting the known effect of TNF as a potent mediator of inflammation. HUMIRA is indicated for the treatment of patients with rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis, among other diseases. HUMIRA is the largest selling therapeutic in the world. HUMIRA is marketed globally by AbbVie Inc., or AbbVie. We expect that U.S. market formation for biosimilar versions of HUMIRA will likely be in the 2022-2023 time frame, subject to marketing approval, patent considerations and litigation timelines.

We are developing M923 as a biosimilar of HUMIRA. Based on our global licensing agreements with AbbVie, and subject to approval by health regulatory authorities, we may launch M923 in the United States as early as November 20, 2023 and in the European Union upon approval. We have decided to delay the filing of a biologics license application for M923 with the U.S. Food and Drug Administration, previously expected in the fourth quarter of 2018, which we believe will not impact the timing of potential U.S. market entry. We also intend to submit a marketing authorization application for M923 with the European Medicines Agency. We are working on identifying a commercialization partner for M923.

M710—Biosimilar EYLEA® (aflibercept) Product Candidate

M710 is being developed in collaboration with Mylan N.V., or Mylan. Subject to development, marketing approval and patent considerations, we expect U.S. market formation for biosimilar versions of EYLEA to occur in the 2023 time frame. We have elected to terminate our collaboration agreement with Mylan with respect to the development of five of our other biosimilar programs, including M834, a proposed biosimilar to ORENCIA®, in order to focus solely on the continued development of M710. On November 19, 2018, we delivered a formal notice of this partial termination to Mylan, as provided in the collaboration agreement.

Our Research Platform

Our approach to drug discovery is focused on identifying unmet medical need in rare immune-related disorders, defining the biology that drives that unmet medical need in order to identify relevant targets, and then using our proprietary biologic protein engineering technologies to design relevant novel product candidates.

Through this we have identified, optimized and are now developing our novel drug candidates: M281, M254 and M230 (the last of which is out-licensed to our partner CSL, a wholly owned indirect subsidiary of CSL Limited). We utilize a suite of research technologies to support the discovery of novel product candidates, including a disease analysis platform where we assess complex human genomic data sets to identify potential disease-modifying targets, and a range of drug design technologies to design the optimal therapeutic agent to modulate those targets. These technologies include not only antibody design and engineering, but also Fc multimerization and in vitro sialylation technology. We believe our sialylation technology can generate several novel product candidates that represent recombinant alternatives to marketed plasma-purified replacement therapies. Additionally, we have leveraged our Fc multimerization technology to identify potential novel product candidates which we believe may improve the immune system's elimination of tumor and other pathologic cells. We believe our Fc multimerization technology can be applied to discover multiple potential product candidates.

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 including, but not limited to, statements about our novel drug candidates for immune-mediated disorders: M281, M254 and M230, and our biosimilar candidates: M923 and M710; the use and efficacy of our novel product candidates and suite of research technologies; the timing of clinical trials, regulatory submissions, potential regulatory approvals and potential launches of our product candidates; potential market size and timing of market formation for our product candidates; our priorities, goals and strategies, including, with respect to our collaboration with Mylan, focusing solely on the continued development of M710; and our

commercialization strategies for our product candidates. Investors are cautioned not to place undue reliance on these forward-looking statements. Each forward-looking statement is subject to risks and uncertainties and other important factors that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include, without limitation, the lengthy and expensive process of clinical drug development, which has an uncertain outcome; failure to raise additional capital as needed; inability to adopt and implement successful strategies and strategic alternatives, including our strategy to focus on the continued development of M710 in our collaboration with Mylan; inability to hire and retain senior management or other highly qualified personnel; unexpected regulatory decisions regarding any of these activities; unexpected expenses or inaccurate financial assumptions or forecasts; additional or increased litigation efforts by our competitors; insufficient resources or failure to prioritize competing projects and efforts; disputes with our collaboration partners; inability to successfully partner the development and commercialization of our product candidates; delays or unfavorable decisions of regulatory agencies; unfavorable regulatory pronouncements; and safety, efficacy or tolerability problems with our product candidates or suite of research technologies. Risks, uncertainties and other important factors also include those discussed under the heading “Risk Factors” and elsewhere in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, in addition to the risk factors that are listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any subsequent SEC filings. We undertake no obligation to update these forward-looking statements to reflect events or circumstances occurring after this Form 8-K. Except as otherwise noted, these forward-looking statements speak only as of the date of this Form 8-K. All forward-looking statements are qualified in their entirety by this cautionary statement.

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: December 6, 2018

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer