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): **November 7, 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 (see General Instruction A.2. below):

☐ 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 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 2.02. Results of Operations and Financial Condition.

On November 7, 2018, Momenta Pharmaceuticals, Inc., a Delaware Corporation ("the Company"), announced its financial results for the quarter ended September 30, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in 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 to be incorporated by reference into any filing of the Company 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 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by Momenta Pharmaceuticals, Inc. on November 7, 2018

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: November 7, 2018

By: /s/Michelle Robertson
Michelle Robertson
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

MOMENTA PHARMACEUTICALS, INC.

301 BINNEY STREET
CAMBRIDGE, MA 02142

T: 617.491.9700 F: 617.621.0430

Momenta Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

CAMBRIDGE, MA — November 7, 2018 - Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) today reported its financial results for the third quarter ended September 30, 2018 and provided a corporate update.

"We recently highlighted our pipeline of novel drug candidates for immune-mediated disorders at our recent R&D Day and, as we look to early 2019, we plan to have two Phase 2 trials of M281 initiated in gMG and HDFN and one Phase 1/2 trial of M254 initiated in ITP," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "To complement the advancement of our novel drug pipeline, we have ongoing revenues from our Glatopa franchise as well as two late-stage biosimilar assets which have the potential to be important revenue drivers to support our novel drug pipeline. We recently executed agreements with AbbVie enabling the global launch of M923, our proposed biosimilar to HUMIRA®, in the European Union and in the United States in November 2023, subject to regulatory approval. Additionally, our research platform is showing broad applicability and we believe it will generate additional pipeline expansion opportunities."

Third Quarter 2018 Highlights and Recent Events

Complex Generics:

Glatopa® Products: a fully substitutable, AP-rated generic version of three-times-a-week COPAXONE® 40 mg/mL and daily COPAXONE 20 mg/mL (glatiramer acetate injection) for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- In the third quarter of 2018, Momenta recorded $13.6 million in product revenues from Sandoz's sales of Glatopa 20 mg/mL and 40 mg/mL products.

Novel Drugs for Rare Autoimmune and Immune-mediated Diseases:

M281 (anti-FcRn): a fully human anti-neonatal Fc receptor (FcRn) aglycosylated immunoglobulin G (IgG1) monoclonal antibody (mAb)

- On October 11, 2018, Momenta presented additional data from its Phase 1 study of M281 in healthy volunteers. M281 exhibited dose-dependent pharmacodynamics, rapid onset of target receptor occupancy, a self-limited IgG decrease to a mean maximum percent reduction of approximately 84% of baseline, and loss of target occupancy and IgG recovery observed at consistent times after the last dose. Single doses up to 60 mg/kg or 15 or 30 mg/kg administered weekly for up to 4 weeks by intravenous infusion were well-tolerated with no serious adverse events, few moderate adverse events (AEs) and a low incidence of infection-related AEs similar to placebo treatment. The full data from the Phase 1 study has been accepted for publication. The Company expects the data to be published before the end of 2018.

- On October 11, 2018 Momenta announced that it plans to commence two Phase 2 proof of concept clinical trials, one in generalized myasthenia gravis (gMG) and one in hemolytic disease of the fetus and newborn (HDFN), in the fourth quarter of 2018.

M230 (CSL730): a recombinant Fc multimer being developed in collaboration with CSL

- CSL's Phase 1 study in healthy volunteers to evaluate the safety and tolerability of M230 is ongoing and is targeted to be completed in 2019.

M254 (hsIgG): a hyper-sialylated immunoglobulin designed to be a higher potency alternative to intravenous immunoglobulin (IVIg) with the potential for enhanced safety and convenience

- The Company is targeting the initiation of a Phase 1/2 proof of concept study in immune thrombocytopenic purpura (ITP) in early 2019, pending regulatory feedback.

Biosimilars:

On October 1, 2018, Momenta announced that as a result of its strategic review the Company plans to advance its two late-stage biosimilar assets, M923, its wholly-owned proposed biosimilar to HUMIRA®, and M710, its proposed biosimilar to EYLEA® being developed in collaboration with Mylan. Momenta has initiated discussions with its collaboration partner, Mylan, to exit its participation in the development of its five other biosimilar programs including M834, a proposed biosimilar to ORENCIA® (abatacept).

M923: a fully-owned proposed biosimilar to HUMIRA® (adalimumab)

- On November 6, 2018 Momenta announced it had entered into a settlement with AbbVie Inc., to enable the commercialization of M923. Under the terms of the agreements and subject to approval by health regulatory authorities, Momenta may launch M923 in the

United States on November 20, 2023 and in Europe upon approval by the European Medicines Agency.

- Momenta plans to submit a biologics license application for M923 with the U.S. Food and Drug Administration in the fourth quarter of 2018 and a marketing authorization application in the European Union in the first half of 2019.

- The Company is working to identify commercialization partners for M923.

M710: a proposed biosimilar to EYLEA® (aflibercept) candidate being developed in collaboration with Mylan

- In August 2018, Mylan initiated a pivotal clinical trial in patients with diabetic macular edema to compare safety, efficacy and immunogenicity of M710 with EYLEA.

Third Quarter 2018 Financial Results

Revenue: In the third quarter of 2018, the Company recorded $13.6 million in product revenues from Sandoz's sales of Glatopa 20 mg/mL and 40 mg/mL products compared to $10.9 million in profit share from Sandoz sales of Glatopa 20 mg/mL for the same period in 2017. The increase in product revenues of $2.7 million, or 25%, was primarily due to a non-recurring deduction of a $5.0 million contractual amount in 2017, offset by lower net sales of Glatopa driven by Mylan N.V.'s entry into the COPAXONE market.

Research and development revenue for the third quarter of 2018 was $1.3 million compared to $13.2 million recorded in the same quarter last year. The decrease in research and development revenue of $11.9 million, or 90%, was primarily due to a $10.0 million milestone achieved in the 2017 period and lower reimbursable expenses for the Company's complex generic programs.

Total revenues for the third quarter of 2018 were $14.9 million compared to $24.1 million for the same period in 2017.

Operating Expenses: Total GAAP operating expenses, were $66.7 million in the third quarter of 2018. In the third quarter of 2018, Momenta recorded $15.5 million of restructuring charges included in total GAAP operating expenses in connection the Company's restructuring announced on October 1, 2018.

Research and development expenses for the third quarter of 2018 were $30.7 million, compared to $37.9 million for the same period in 2017. The decrease of $7.2 million, or 19%, was primarily due to a decrease in external R&D expenses for M923 offset by increases in spending for M281 and M230.

General and administrative expenses for the third quarter of 2018 were $20.4 million, compared with $20.7 million for the same period in 2017. General and administrative expenses for the third quarter of 2018 includes professional fees of $1.0 million incurred in connection with the Company's strategic review.

Third quarter non-GAAP operating expenses were $45.7 million. Non-GAAP operating expenses is total operating expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense, restructuring costs and collaborative reimbursement revenues. See "Non-GAAP Financial Information and Other Disclosures" and the table below entitled "Reconciliation of GAAP Results to Non-GAAP Financial Measures" for a reconciliation of GAAP operating expense to non-GAAP operating expense.

Net Loss: The Company reported a net loss of $50.3 million, or $0.65 per share for the third quarter of 2018 compared to a net loss of $33.2 million, or $0.44 per share for the same period in 2017. The net loss for the third quarter includes restructuring charges of $15.5 million.

Cash Position: At September 30, 2018, Momenta had $281.6 million in cash, cash equivalents and marketable securities compared to $321.2 million at June 30, 2018.

2018 Financial Guidance

Momenta provides non-GAAP operating expense guidance, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP financial measures. Refer to the section of this press release below entitled "Non-GAAP Financial Information and Other Disclosures" for further discussion of this subject.

Non-GAAP operating expense is total operating expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense, restructuring costs, and collaborative reimbursement revenues. Today, Momenta is providing updated non-GAAP operating expense guidance of approximately $230 - $240 million for 2018 and $45 - $55 million for the fourth quarter of 2018. Approximately $1.4 million in additional charges related to the restructuring are anticipated to be recorded in the quarter ending December 31, 2018. The Company expects to continue to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. The Company also estimates that collaborative reimbursement revenues will be approximately $0 - $2 million in the fourth quarter of 2018.

Non-GAAP Financial Information and Other Disclosures

Momenta uses a non-GAAP financial measure, non-GAAP operating expense, to provide operating expense guidance. Momenta believes this non-GAAP financial measure is useful

to investors because it provides greater transparency regarding Momenta's operating performance as it excludes non-cash stock compensation expense, restructuring costs and collaborative reimbursement revenues. This non-GAAP financial measure should not be considered a substitute or an alternative to GAAP total operating expense and should not be considered a measure of Momenta's liquidity. Instead, non-GAAP operating expense should only be used to supplement an understanding of Momenta's operating results as reported under GAAP. Momenta has not provided GAAP reconciliation for its forward-looking non-GAAP annual or quarterly operating expense because Momenta cannot reliably predict without unreasonable efforts the timing or amount of the factors that substantially contribute to the projection of stock compensation expense, which is excluded from the forward-looking non-GAAP financial measure. The Company has provided the estimated reconciling information that is available without unreasonable effort in the section of this press release above entitled "2018 Financial Guidance."

Conference Call Information

Management will host a conference call and webcast today at 8:00 am ET to discuss these results and provide an update on the Company. A live webcast of the conference call may be accessed on the "Investors" section of the Company's website, www.momentapharma.com. An archived version of the webcast will be posted on the Momenta website approximately two hours after the call.

To access the call you may also dial (877) 224-9084 (domestic) or (720) 545-0022 (international) prior to the scheduled conference call time and provide the access code 3079348. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through November 14, 2018. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 3079348.

About Momenta

Momenta is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases. Momenta's lead product candidate, M281, is a potentially best-in-class anti-FcRn antibody; M254, is a hyper-sialylated human immunoglobulin (hsIgG) designed as a high potency alternative to intravenous immunoglobulin (IVIg); and M230 (CSL730), is a potential first-in-class novel recombinant Fc multimer being developed in collaboration with CSL. Momenta also has a focused pipeline of two biosimilar candidates: M710, a proposed biosimilar to EYLEA® being developed in collaboration with Mylan, and M923, Momenta's wholly-owned proposed biosimilar to HUMIRA®. Momenta's two FDA-approved complex

generic products, enoxaparin sodium injection and Glatopa® (glatiramer acetate injection), are marketed by its collaboration partner, Sandoz.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release.

Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

Forward Looking Statements

Statements in this press release 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 our strategic plans and the restructuring resulting from our strategic review; the timing of our regulatory filings for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates; development strategies and timelines; the Company's ability to meet its development and strategic goals; market potential and product revenues of our products and product candidates, including the potential future revenue from Glatopa 20 and 40 mg profit share, M923 and M710; timing of clinical trials and the timing, availability and announcement of data and results; future legal proceedings; expectations regarding accounting treatment for and recognition of consideration and revenues under the Company's collaborations; reconciling information; non-GAAP operating expense guidance and our anticipated collaborative reimbursement revenues and restructuring charges. Forward-looking statements may be identified by words and phrases such as "advance," "anticipate," 'being developed," "believe," "continue," "expect," "guidance," "look forward to," "may," "plan," "possible," "potential," "progress," "propose," "remains," "target," "will," "working toward" and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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 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 press release as of this date and assumes no obligations to update the information included in this press

release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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MOMENTA PHARMACEUTICALS, INC.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 281,573	$ 379,890
Collaboration receivable	13,835	15,048
Restricted cash	19,349	23,032
Other assets	38,527	41,461
Total assets	$ 353,284	$ 459,431
Liabilities and Stockholders' Equity		
Current liabilities	$ 54,445	$ 44,487
Deferred revenue, net of current portion	33,527	30,751
Other long-term liabilities	16,555	10,039
Stockholder's equity	248,757	374,154
Total liabilities and stockholders' equity	$ 353,284	$ 459,431

MOMENTA PHARMACEUTICALS, INC.
Unaudited Condensed Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenues:				
Product revenue	$ 13,621	$ 10,890	$ 28,921	$ 53,434
Research and development revenue	1,263	13,200	3,846	20,840
Total collaboration revenue	14,884	24,090	32,767	74,274
Operating expenses:				
Research and development	30,727	37,914	95,309	113,078
General and administrative	20,437	20,703	63,580	66,380
Restructuring	15,535	—	15,535	—
Other	—	—	30,000	—
Total operating expenses	66,699	58,617	204,424	179,458
Loss from operations	(51,815)	(34,527)	(171,657)	(105,184)
Other income, net	1,515	1,339	3,841	3,329
Net loss	$ (50,300)	$ (33,188)	$ (167,816)	$ (101,855)
Net loss per share:				
Basic and diluted	$ (0.65)	$ (0.44)	$ (2.20)	$ (1.40)
Shares used in calculating net loss per share				
Basic and diluted	77,229	74,611	76,415	72,585
Comprehensive loss	$ (50,163)	$ (33,136)	$ (167,840)	$ (101,894)

MOMENTA PHARMACEUTICALS, INC.

Reconciliation of GAAP Results to Non-GAAP Financial Measures

(In thousands)

(unaudited)

A reconciliation of historical GAAP operating expenses to Non-GAAP operating expenses is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
GAAP operating expenses	$ 66,699	$ 58,617	$ 204,424	$ 179,458
Adjustments:				
Restructuring	(15,535)	—	(15,535)	—
Non-cash stock compensation expense	(4,870)	(4,916)	(14,916)	(16,309)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(632)	(2,078)	(1,950)	(6,541)
Non-GAAP operating expenses	$ 45,662	$ 51,623	$ 172,023	$ 156,608