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): **February 22, 2019**

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 February 22, 2019, Momenta Pharmaceuticals, Inc. ("the Company"), announced its financial results for the year ended December 31, 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 February 22, 2019

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: February 22, 2019

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 Fourth Quarter and Full Year 2018 Financial Results

—Ended 2018 with a cash position of $449.0 million —

— Phase 2 trials of M281 in myasthenia gravis (MG) and hemolytic disease of the fetus and newborn (HDFN) underway; First healthy volunteer dosed in Phase 1/2 trial of M254 in immune thrombocytopenia (ITP) —

CAMBRIDGE, MA — February 22, 2019 - Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), a biotechnology company focused on discovering and developing novel biologic therapeutics to treat rare immune-mediated diseases, today reported its financial results for the fourth quarter and full year ended December 31, 2018.

"In 2018 we transformed our company to focus on discovering and developing new therapies to treat rare immune-mediated disorders. We have since made important progress, as we have commenced two Phase 2 clinical trials of our anti-FcRn antibody, M281, and dosed the first healthy volunteer in part 1 of a Phase 1 / 2 clinical trial of our hypersialylated IgG candidate M254. Meanwhile, our legacy business continues to provide value in the form of revenue from the Glatopa franchise and we continue to work with Mylan to advance the Phase 3 clinical trial of M710, our biosimilar EYLEA candidate," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals.

"Looking forward, as we focus on operational execution in the year ahead, we remain confident in the ability of our differentiated platforms to produce best-in-class immune-mediated therapeutics and are well-capitalized to execute on our development plans," Wheeler continued.

Fourth Quarter 2018 Highlights, Recent Events and Anticipated Upcoming Milestones

Novel Therapeutics Pipeline:

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

- The Company has commenced two Phase 2 clinical studies of M281 in gMG and HDFN with topline results anticipated in 2020 and 2021, respectively. The Company also plans to initiate a third study of M281 in an additional autoimmune indication in 2019.
- In February 2019, the Company presented research at the Society for Maternal-Fetal Medicine 39th Annual Pregnancy Meeting in Las Vegas, NV highlighting the ability of M281 to inhibit transfer of immunoglobulin G from maternal to fetal circulation in an *ex vivo* placental perfusion model.
- In November 2018, the Company announced the publication of results from a Phase 1 clinical trial of M281 in healthy volunteers in the peer-reviewed journal Clinical Pharmacology & Therapeutics.

M254 (hsIgG): a hypersialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg)

- In January 2019, the Company announced that the first subject was dosed in the Phase 1/2 clinical trial in ITP. The multi-part study will first enroll healthy volunteers and includes single and multiple dose studies, and a randomized cross-over study comparing M254 to IVIg. Preliminary clinical data is expected in 2020.

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

- The Phase 1 clinical trial in healthy volunteers to evaluate the safety and tolerability of M230 continues. Momenta's partner, CSL expects to complete the Phase 1 study by the end of 2019.

Legacy Products:

Glatopa® 20 mg and 40 mg: FDA approved generic versions of COPAXONE 20 mg and 40 mg, developed and commercialized in collaboration with Sandoz

- In the fourth quarter of 2018, Momenta recorded $10.8 million in product revenue from Sandoz's sales of Glatopa products.

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

- In November 2018, the Company announced license agreements with AbbVie, providing worldwide rights for the launch of M923. Under the terms of the agreements, and subject to approval by health regulatory authorities, Momenta may launch M923 worldwide based on agreed-to launch dates, including in the United States (U.S.) in November 2023.

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. In November 2018, Momenta provided formal notice of termination for all other biosimilar candidates previously subject to the collaboration agreement with Mylan.

Corporate:

- In December 2018, Momenta announced the closing of a public offering of 20.0 million shares of its common stock at the price of $11.50 per share. Aggregate gross proceeds from the offering were $230.0 million.

Fourth Quarter and Full Year 2018 Financial Results

Revenue: In the fourth quarter of 2018, the Company recorded $10.8 million in product revenue from Sandoz's sales of Glatopa, compared to $13.1 million for the same period in 2017. For the year ended December 31, 2018, the Company recorded $39.7 million in product revenue from Sandoz's sales of Glatopa, compared to $66.8 million for the same period in 2017. The decrease in product revenue of $2.3 million, or 17.6% from the fourth quarter of 2017 to the fourth quarter of 2018 was primarily due to continued competition. The decrease in product revenue of $27.2 million, or 41.3% from the year ended 2017 to the year ended 2018 was primarily due to continued competition and reflects a $9.8 million deduction of our 50% share of GLATOPA 40 mg/mL inventory written off by Sandoz.

Research and development revenue for the fourth quarter of 2018 was $32.1 million, compared to $51.2 million in the same quarter in 2017. The decrease in research and development revenue of $19.2 million, or 37.3%, was primarily due to the recognition of an upfront payment of $50.0 million from CSL, offset in part by an increase of revenue recognized related to Mylan's upfront payment of $28.4 million due to the partial termination of the Mylan collaboration agreement and the resulting determination that certain performance obligations under the agreement have been partially satisfied. For the year ended December 31, 2018, research and development revenue was $35.9 million compared to $72.1 million recorded in the same period in 2017. The decrease in research and development revenue of $36.2 million, or 50.2%, was primarily due to recognition of the $50.0 million upfront payment from CSL and the $10.0 million commercial milestone from Sandoz recognized in 2017 that was non-recurring in 2018. This was offset in part by an increase of revenue recognized related to Mylan's upfront payment of $28.4 million due to the partial termination of the Mylan collaboration agreement and the resulting determination that certain performance obligations under the agreement have been partially satisfied.

Total revenue for the fourth quarter of 2018 was $42.8 million compared to $64.6 million for the same period in 2017. For the year ended December 31, 2018, total revenue was $75.6 million compared to $138.9 million for the same period in 2017.

Operating Expenses: Total GAAP operating expenses were $52.5 million in the fourth quarter of 2018. For the year ended December 31, 2018, total GAAP operating expenses were $256.9 million.

Research and development expenses for the fourth quarter of 2018 were $28.7 million, compared to $36.1 million for the same period in 2017. The decrease of $7.4 million, or 20.5%, was primarily due to decreased spending on the Company's biosimilar programs. For the year ended December 31, 2018, research and development expenses were $124.0 million, compared to $149.2 million for the same period in 2017. The decrease of $25.2 million, or 16.9%, was due to decreased spending on the Company's biosimilar programs of $43.5 million. These decreases were partially offset by increases in spend of $23.9 million on the Company's novel therapeutic programs.

General and administrative expenses for the fourth quarter of 2018 were $21.5 million, compared with $15.8 million for the same period in 2017. The increase of $5.7 million, or 36.1%, was primarily driven by increased legal costs and depreciation. For the year ended December 31, 2018, general and administrative expenses were $85.1 million, compared to $82.2 million for the same period in 2017. The increase of $2.9 million, or 3.5%, was driven by net of increased rent expense of $3.3 million related to occupancy of new premises, one-time costs related to our strategic review of $3.2 million and depreciation of $3.6 million as the Company evaluated estimates of the useful lives of depreciable assets, partially offset by decreases of $4.6 million of legal costs relating to our ongoing litigation and personnel salaries of $2.3 million due in part to the recent workforce reduction.

Fourth quarter non-GAAP operating expense was $47.2 million, within the range of previously provided guidance of $45 - $55 million. Full year 2018 non-GAAP operating expense was $219.2 million. Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. 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 Income (Loss): The Company reported a net loss of $8.2 million, or $0.10 per share for the fourth quarter of 2018 compared to a net income of $13.8 million, or $0.18 per share for the same period in 2017. For the year ended December 31, 2018, the Company reported a net loss of $176.1 million, or $2.26 per share compared to a net loss of $88.1 million, or $1.20 per share for 2017.

Cash Position: At December 31, 2018, Momenta had $449.4 million in cash, cash equivalents and marketable securities compared to $281.6 million at September 30, 2018, reflecting the December 2018 common stock financing.

2019 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, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. Momenta is providing quarterly non-GAAP operating expense guidance of $45 - $55 million for 2019.

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 expense and collaborative reimbursement revenue. 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 "2019 Financial Guidance."

Conference Call Information

Management will host a conference call and webcast today at 8:30 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. Please go to the site at least 15 minutes prior to the call in order to register, download, and install any necessary software. 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 7484068. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through 7484068. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 7484068.

About Momenta

Momenta Pharmaceuticals is a biotechnology company focused on discovering and developing novel biologic therapeutics to treat rare immune-mediated diseases and advancing its late stage biosimilars and is headquartered in Cambridge, MA.

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

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 statements about the timing of our regulatory filings for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates; development timelines; the Company's ability to meet its development and strategic goals; market potential and revenue of our products and product candidates, design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, safety, potency, tolerability, convenience and commercial potential of our product candidates, including their potential as best-in-class agents; future legal proceedings; expectations regarding accounting treatment for and recognition of consideration and revenue under the Company's collaborations; reconciling information; non-GAAP operating expense guidance; and anticipated collaborative reimbursement revenue. 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 September 30, 2017, 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.

INVESTOR CONTACT:
Patty Eisenhaur
Momenta Pharmaceuticals
1-617-395-5189
IR@momentapharma.com

MEDIA CONTACT:
Karen Sharma
MacDougall Biomedical Communications
1-781-235-3060
Momenta@macbiocom.com

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 449,411	$ 379,890
Collaboration receivable	11,371	15,048
Restricted cash	37,898	23,032
Other assets	32,883	41,461
Total assets	$ 531,563	$ 459,431
Liabilities and Stockholders' Equity		
Current liabilities	$ 51,511	$ 44,487
Deferred revenue, net of current portion	1,774	30,751
Other long-term liabilities	17,270	10,039
Stockholders' equity	461,008	374,154
Total liabilities and stockholders' equity	$ 531,563	$ 459,431

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Statements of Operations and Comprehensive Loss

(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Collaboration revenue:				
Product revenue	$ 10,763	$ 13,369	$ 39,684	$ 66,803
Research and development revenue	32,059	51,239	35,905	72,079
Total collaboration revenue	42,822	64,608	75,589	138,882
Operating expenses:				
Research and development	28,695	36,148	124,004	149,226
General and administrative	21,525	15,827	85,105	82,207
Other	—	—	30,000	—
Restructuring	2,272	—	17,807	—
Total operating expenses	52,492	51,975	256,916	231,433
Loss from operations	(9,670)	12,633	(181,327)	(92,551)
Other income, net	1,426	1,126	5,266	4,455
Net income (loss)	$ (8,245)	$ 13,759	$ (176,061)	$ (88,096)
Earnings (net loss) per share:				
Basic	$ (0.10)	$ 0.18	$ (2.26)	$ (1.20)
Diluted	$ (0.10)	$ 0.18	$ (2.26)	$ (1.20)
Shares used in calculating net loss per share				
Basic	82,087	74,770	77,845	73,136
Diluted	82,087	75,033	77,845	73,136
Comprehensive income (loss)	$ (8,168)	$ 13,572	$ (176,008)	$ (88,322)

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
GAAP operating expenses	$ 52,492	$ 51,975	$ 256,916	$ 231,433
Adjustments:				
Restructuring	(2,273)	—	(17,807)	—
Non-cash stock compensation expense	(2,498)	183	(17,414)	(16,127)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(518)	(523)	(2,468)	(7,064)
Non-GAAP operating expenses	$ 47,203	$ 51,635	$ 219,227	$ 208,242