

**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): October 31, 2019

Momenta Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

000-50797

(Commission
File Number)

04-3561634

(IRS Employer
Identification No.)

301 Binney Street, Cambridge, MA

(Address of Principal Executive Offices)

02142

(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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	MNTA	The Nasdaq Global Select Market

Item 2.02. Results of Operations and Financial Condition.

On October 31, 2019, Momenta Pharmaceuticals, Inc., a Delaware corporation (“the Company”), announced its financial results for the quarter ended September 30, 2019. 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 October 31, 2019](#)

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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: October 31, 2019

By: /s/Michelle Robertson

Michelle Robertson
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

MOMENTA
PHARMACEUTICALS,
INC.

301 BINNEY STREET
CAMBRIDGE, MA 02142

T: 617.491.9700
F: 617.621.0430

Momenta Pharmaceuticals Reports Third Quarter 2019 Financial and Operating Results

CAMBRIDGE, MA - October 31, 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 third quarter ended September 30, 2019.

“Our focus in 2019 is on the execution of our clinical programs as they advance toward proof of concept,” said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. “Looking ahead to 2020, we anticipate key readouts across our novel auto- and alloimmune programs, including proof-of-concept data from M254 in ITP and nipocalimab in MG. Importantly, both of these agents have the potential to reshape the treatment landscape for a range of large market, IgG-mediated diseases.”

Third Quarter 2019 Highlights, Recent Events and Anticipated Upcoming Milestones

Novel Therapeutics Pipeline:

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

- Vivacity-MG, the Company’s Phase 2 clinical study of nipocalimab in generalized myasthenia gravis (gMG), continues to enroll patients. The Company expects to report top-line data from this study in the second or third quarter of 2020.

- Unity, the Company's global multi-center Phase 2 clinical study of nivalimab in hemolytic disease of the fetus and newborn (HDFN), is active and enrolling patients. Nivalimab has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for this indication and the Company expects to report top-line from this study data in 2021.
- Energy, the Company's adaptive Phase 2/3 clinical study of nivalimab in Warm Autoimmune Hemolytic Anemia (wAIHA) commenced in the third quarter 2019. The Company is activating clinical sites in both the United States and European Union and is actively recruiting patients. Nivalimab has been granted Fast Track designation by the FDA in this indication and the Company expects to report top-line data from this study around the end of 2021.

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

- The Company's multi-part Phase 1/2 clinical trial in idiopathic thrombocytopenic purpura (ITP) has completed Part A and is progressing through Part B, which is evaluating M254 in a single ascending dose (SAD) cohort of ITP patients. Parts C and D include a randomized cross-over study comparing M254 to IVIg and a multiple ascending dose (MAD) study of M254, respectively. Enrollment is ongoing and the Company expects to report preliminary data from this study in the first half of 2020.

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

- A Phase 1 clinical trial to evaluate the safety and tolerability of M230 in healthy volunteers is ongoing and Momenta's partner, CSL, looks forward to introducing a subcutaneous formulation into the phase 1 program. We expect to have data regarding this formulation in the next calendar year.

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 third quarter of 2019, Momenta recorded \$5.6 million in product revenue from Sandoz's sales of Glatopa products.

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

- Mylan continues its pivotal clinical trial in patients with diabetic macular edema to compare safety, efficacy and immunogenicity of M710 with EYLEA.

Corporate:

- In September 2019, the Company announced the appointment of Donna Grogan, M.D. to its Board of Directors.

Third Quarter 2019 Financial Results

Revenue:

In the third quarter of 2019, the Company recorded \$5.6 million in product revenue from Sandoz's sales of Glatopa. In the third quarter of 2018, the Company recorded \$13.6 million in product revenue, net a deduction of \$0.2 million for legal fees and includes 1.7 million received by Momenta for the Pfizer settlement. The decrease in product revenue from the prior year period was primarily due to continued competition.

Research and development revenue for the third quarter of 2019 was \$0.8 million, compared to \$1.3 million in the same quarter in 2018. The decrease in research and development revenue of \$0.4 million, or 34%, was primarily due to lower reimbursement revenue for Glatopa expenses.

Total revenue for the third quarter of 2019 was \$6.4 million compared to \$14.9 million for the same period in 2018.

Operating Expenses:

Research and development expenses for the third quarter of 2019 were \$46.1 million, compared to \$30.7 million for the same period in 2018. The increase of \$15.3 million, or 50%, was primarily due to an increase in manufacturing and clinical trial costs for nipocalimab and M254, offset in part by lower personnel costs following the Company's workforce reduction in the fourth quarter of 2018 and lower lease costs.

General and administrative expenses for the third quarter of 2019 were \$20.1 million, compared with \$20.4 million for the same period in 2018. The decrease of \$0.4 million, or 2%, was primarily due to lower depreciation costs.

In July 2019, Momenta entered into an amendment to its office and laboratory space lease at 320 Bent Street in Cambridge, Massachusetts, reducing the Company's footprint at the location. During the quarter, the company recognized a noncash gain of \$13.7 million, reflecting the reduction in the lease liability and the related right-of-use asset.

Total GAAP operating expenses were \$52.5 million in the third quarter of 2019. Third quarter 2019 non-GAAP operating expense was \$45.7 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 \$44.5 million, or \$0.45 per share for the second quarter of 2019 compared to a net loss of \$50.3 million, or \$0.65 per share for the same period in 2018.

Liquidity: At September 30, 2019, Momenta had \$325.9 million in cash, cash equivalents, marketable securities, and reflects the addition of \$36.1 million related to the release of a bond following a settlement agreement with Amphastar Pharmaceuticals. This compares to \$449.4 million at December 31, 2018 in cash, cash equivalents, and marketable securities.

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 \$50 - \$60 million for the fourth quarter 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 3067995.

About Momenta

Momenta Pharmaceuticals is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases and advancing its late stage biosimilar portfolio. The company 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.

The Company's 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 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; 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 June 30, 2019, 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 Eisenhour
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)

	September 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	\$ 325,862	\$ 449,411
Collaboration receivable	5,670	11,371
Restricted cash	1,849	37,898
Other assets	64,387	32,883
Total assets	<u>\$ 397,768</u>	<u>\$ 531,563</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 40,581	\$ 51,511
Deferred revenue, net of current portion	1,183	1,774
Other long-term liabilities	80,080	17,270
Stockholder's equity	275,924	461,008
Total liabilities and stockholders' equity	<u>\$ 397,768</u>	<u>\$ 531,563</u>

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,	
	2019	2018	2019	2018
Collaboration revenues:				
Product revenue	\$ 5,551	\$ 13,621	\$ 11,236	\$ 28,921
Research and development revenue	840	1,263	4,450	3,846
Total collaboration revenue	6,391	14,884	15,686	32,767
Operating expenses:				
Research and development	46,105	30,727	106,208	95,309
General and administrative	20,081	20,437	90,896	63,580
Other operating expense	—	—	42,936	30,000
Restructuring	19	15,535	177	15,535
Gain on lease modification	(13,720)	—	(13,720)	—
Total operating expenses	52,485	66,699	226,497	204,424
Loss from operations	(46,094)	(51,815)	(210,811)	(171,657)
Other income, net	1,551	1,515	7,456	3,841
Net loss	<u>\$ (44,543)</u>	<u>\$ (50,300)</u>	<u>\$ (203,355)</u>	<u>\$ (167,816)</u>
Net loss per share:				
Basic and diluted	\$ (0.45)	\$ (0.65)	\$ (2.06)	\$ (2.20)
Shares used in calculating net loss per share				
Basic and diluted	98,709	77,229	98,501	76,415
Comprehensive loss	\$ (44,601)	\$ (50,163)	\$ (202,807)	\$ (167,840)

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,	
	2019	2018	2019	2018
GAAP operating expenses	\$ 52,485	\$ 66,699	\$ 226,497	\$ 204,424
Adjustments:				
Restructuring	(19)	—	(177)	—
Non-cash stock compensation expense	(6,689)	(10,126)	(13,825)	(20,172)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(119)	(632)	(882)	(1,943)
Non-GAAP operating expenses	<u>\$ 45,658</u>	<u>\$ 55,941</u>	<u>\$ 211,613</u>	<u>\$ 182,309</u>