MOMENTA PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 02/21/17 for the Period Ending 02/21/17

Address	675 WEST KENDALL STREET CAMBRIDGE, MA 02142
Telephone	617 491-9700
CIK	0001235010
Symbol	MNTA
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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 21, 2017**

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:

☐ 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))

Item 2.02 Results of Operations and Financial Condition.

On February 21, 2017, Momenta Pharmaceuticals, Inc., a Delaware corporation ("Momenta"), announced its financial results for the year ended December 31, 2016. 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 Momenta 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 21, 2017.

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: February 21, 2017

By: /s/ Scott M. Storer
Scott M. Storer
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Momenta Pharmaceuticals, Inc. on February 21, 2017.

Exhibit 99.1

MOMENTA PHARMACEUTICALS, INC. 675 WEST KENDALL STREET T: 617.491.9700 F: 617.621.0430

CAMBRIDGE, MA 02142 WWW.MOMENTAPHARMA.COM

Momenta Pharmaceuticals Reports Fourth Quarter and Year End 2016 Financial Results

CAMBRIDGE, MA — February 21, 2017 — Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) today reported its financial results for the fourth quarter and year ended December 31, 2016.

For the fourth quarter of 2016, the Company reported total revenues of $34.2 million, including $15.8 million in product revenues from Sandoz's sales of Glatopa ® 20 mg (glatiramer acetate injection), net of a deduction of $3.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses. For the year ended December 31, 2016, the Company reported total revenues of $109.6 million, including $74.6 million in product revenues from Sandoz's sales of Glatopa 20 mg, net a deduction of $3.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses. Momenta reported net income of $41.5 million, or $0.60 per share for the fourth quarter of 2016, compared to a net loss of $(29.2) million, or $(0.43) per share for the same period in 2015. For the year ended December 31, 2016, the Company reported a net loss of $(21.0) million, or $(0.31) per share compared to a net loss of $(83.3) million, or $(1.32) per share for the same period in 2015. At December 31, 2016, the Company had cash, cash equivalents, and marketable securities of $353.2 million compared to $350.0 million at December 31, 2015.

"In 2016, Momenta reported significant advances across our portfolio. In early January 2017, we announced a significant research collaboration and license agreement with CSL for M230, our SIF3 novel therapeutic product candidate, and potential future Fc multimer programs. We also announced an agreement with Shire for the early return of full rights to the M923 program, our biosimilar HUMIRA ® candidate. We were also pleased by the District Court's decision to invalidate the four method of use patents litigated by Teva to block Sandoz's potential launch of our Glatopa 40 mg product," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We are fully committed to work with Sandoz and Pfizer to resolve the recently announced warning letter. With the potential for the approval and launch of Glatopa 40 mg and with multiple data readouts expected across our biosimilar and novel programs this year, we believe 2017 could be a transformative year for Momenta."

Fourth Quarter Highlights and Recent Events

Complex Generics:

Glatopa 20 mg: First FDA-approved, substitutable generic daily COPAXONE ® 20 mg for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- On February 17, 2017, the Company announced that Sandoz's contracted fill/finish manufacturing partner for Glatopa, Pfizer, has received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the Glatopa 20 mg product that is currently marketed by Sandoz in the United States.

- In the fourth quarter of 2016, Momenta recorded $15.8 million in product revenues from Sandoz's Glatopa 20 mg sales. For the year ended December 31, 2016, the Company recorded $74.6 million in product revenues from Sandoz's sales of Glatopa 20 mg reflecting $78.2 million in profit share.

Glatopa 40 mg: Designed to be a generic version of three times-a-week COPAXONE ® 40 mg (glatiramer acetate injection) for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- The Abbreviated New Drug Application (ANDA) submitted by Sandoz for a three-times-a-week generic COPAXONE 40 mg is under U.S. Food and Drug Administration (FDA) review. An approval of the application may be dependent on the satisfactory resolution of the compliance observations stated in the FDA warning letter issued to Pfizer, the contracted fill/finish manufacturer for Glatopa. The Company believes that an approval in the first quarter of 2017 is unlikely.

- On January 30, 2017, the United States District Court for the District of Delaware found Teva Pharmaceutical's U.S. Patent Nos. 8,232,250; 8,399,413; 8,969,302; and 9,155,776 for COPAXONE 40 mg invalid as obvious over the prior art. Teva has appealed the decision to U.S. Court of Appeals for the Federal Circuit (CAFC). The Company expects a decision from the CAFC will be issued within 12 to 18 months and plans to aggressively defend against Teva's appeal.

- Teva has asserted infringement claims under two additional patents (U.S. Patent Nos. 9,155,775 ("the '775 patent)" and 9,402,874 ("the '874 patent"), which claims Momenta believes to be invalid, not infringed and unenforceable. On February 17, 2017, Teva filed a motion for preliminary injunctive relief under the '775 patent seeking to enjoin a launch of Glatopa 40 mg. The Company plans to vigorously defend its freedom to launch and oppose these actions. As part of this defense, the Company has filed an action in the United States Court for the District of Delaware seeking a declaratory judgment of invalidity, non-infringement and unenforceability for the '775 patent.

Biosimilars:

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

- In December 2016, Momenta signed an early termination of the collaboration agreement with Baxalta, a wholly-owned subsidiary of Shire plc, to develop and commercialize M923. In January, the Company received a one-time asset return payment of $51.2 million from Shire intended to fund Momenta's estimated costs of performing the development activities that would have been performed by Shire through the original termination date of September 27, 2017.

- In November 2016, the Company announced positive Phase 3 top-line results of M923 in patients with moderate-to-severe chronic plaque psoriasis. Momenta is targeting mid-2017 for the first submission for marketing approval of M923. Subject to marketing approval and patent considerations, the Company expects first commercial launch of M923 to be as early as 2020 timeframe.

M834: a proposed biosimilar to ORENCIA ® (abatacept) being developed in collaboration with Mylan

- In November 2016, Momenta and its collaboration partner Mylan announced the initiation of a Phase 1 clinical trial for M834. The companies plan to report top-line data from the Phase 1 trial in the second half of 2017.

- In November 2016, Momenta received a $25.0 million development milestone payment from Mylan to be applied toward the funding of Mylan's 50% share of collaboration expenses.

- On December 22, 2016, the U.S. Patent and Trademark Office's Patent Trial and Appeal Board issued their decision upholding the validity of U.S. Patent No. 8,476,239, related to Bristol Myers Squibb's ORENCIA (abatacept) product following the Company's Inter Partes Review challenging this patent. The Company is considering its options for appeal to the U.S. Court of Appeals for the Federal Circuit.

M710: a biosimilar candidate being developed in collaboration with Mylan

- In December 2016, in connection with a joint decision to continue development of M710, Momenta received a $35.0 million milestone payment from Mylan to be applied toward the funding of Mylan's 50% share of collaboration expenses.

Novel Drugs for Autoimmune Indications:

Momenta's novel autoimmune portfolio includes two recombinant molecules: M230, a Selective Immunomodulator of Fc receptors (SIF3) and M281, an anti-FcRn monoclonal antibody. Momenta is also developing a hyper-sialylated IVIg (M254) as a potential high potency version of IVIg that is currently in pre-clinical development.

M230 (SIF3): a Selective Immunomodulator of Fc receptors

- On January 5, 2017, the Company announced that it has entered into a worldwide license agreement and an exclusive research collaboration with CSL to develop and commercialize Fc multimer proteins, including Momenta's M230, which is expected to enter the clinic in 2017. In addition to advancing M230, the agreement initiates a research collaboration to develop additional Fc multimer proteins that may originate from Momenta's or CSL's research.

- On February 17, 2017 the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act) in connection with license agreement and research collaboration with CSL expired. Under the agreement, CSL is obligated to pay Momenta a $50 million upfront cash payment within 30 days of the effective date of February 17, 2017.

M281 (anti-FcRn): a fully human monoclonal antibody (mAb) targeting the neonatal Fc receptor (FcRn)

- The Company has successfully completed the Phase 1 single ascending dose study in healthy volunteers. In the SAD portion of the study, a single dose of 30 mg/kg achieved up to 80% reduction of circulating IgG antibodies. M281 was well-tolerated and to date no serious adverse events have been observed. The multiple ascending dose portion of the study was initiated in January 2017.

- The Company plans to report the full data from the single and multiple ascending dose portions of the study in the second half of 2017.

Fourth Quarter and Year End 2016 Financial Results

Total revenues for the fourth quarter of 2016 were $34.2 million compared to $22.4 million for the same period in 2015. For the fourth quarter of 2016, the Company recorded $15.8 million in product revenues from Sandoz's sales of Glatopa 20 mg reflecting $19.4 million in profit share, net of a deduction of $3.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $15.6 million for the same period in 2015. Research and development revenue for the fourth quarter of 2016 of $18.4 million includes $14.6 million of collaborative revenue representing the remaining unamortized balance of the $40.0 million upfront and license payments from Baxalta. Research and development revenue for the same period in 2015 of $4.6 million includes $2.4 million of amortization of Baxalta's upfront and license payments.

For the year ended December 31, 2016, total revenues were $109.6 million compared to $89.7 million for 2015. Total revenues for full year 2016 include $74.6 million in product revenue earned from Sandoz's sales of Glatopa 20 mg, net a deduction of $3.6 million in reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $43.4 million in product revenue earned from Sandoz's sales of Glatopa 20 mg for the full year 2015, net of a deduction of $9.1 million in reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses. The increase in product revenues of $31.2 million, or 72%, from 2015 to 2016 was primarily due to a higher number of Glatopa 20 mg units sold. Research and development revenue for 2016 of $35.0 million includes $22.0 million of collaborative revenue representing the remaining unamortized balance of the $40.0 million upfront and license payments from Baxalta. Research and development revenue for 2015 of $41.1 million includes $20.0 million in milestone payments earned upon sole FDA approval and first commercial sale of Glatopa 20 mg.

Research and development expenses for the fourth quarter of 2016 were $26.4 million, compared to $37.6 million for the same period in 2015. The decrease of $11.2 million, or 30%, from the 2015 period was due to decreases of $6.8 million for Mylan's 50% share of biosimilar collaboration costs, and $3.3 million due to the discontinuation of the necuparanib development program. For the year ended December 31, 2016, research and development expenses were $119.9 million compared to $126.0 million for the year ended 2015. The decrease of $6.1 million, or 5%, in research and development expenses from 2015 to 2016 resulted from a decrease of $26.5 million for Mylan's 50% share of biosimilar collaboration costs, partially offset by increases of $11.9 million in third-party research, process development, and nonclinical study costs to advance our biosimilar and novel autoimmune programs; $4.9 million in personnel-related expenses, of which $2.5 million is due to increased headcount and $2.4 million is driven by stock compensation; and $2.9 million in costs for the Phase 1 clinical studies of M281 and M834.

General and administrative expenses for the quarter ended December 31, 2016 were $18.2 million, compared with $14.4 million for the same period in 2015. The increase of $3.8 million, or 26%, from the 2015 period was primarily due to increases of $1.5 million in personnel-related expenses and $2.1 million in legal and professional fees. For the year ended December 31, 2016, general and administrative expenses were $64.5 million, compared to $48.1 million for the year ended 2015. The increase of $16.4 million, or 34%, resulted from increases of $9.6 million in personnel-related expenses, of which $5.1 million is due to increased headcount and $4.5 million is driven by stock compensation, and $7.2 million in professional fees primarily for legal, consulting and recruiting costs. The increases were offset by a decrease of $1.3 million for Mylan's 50% share of biosimilar collaboration costs.

Other Income for the fourth quarter of 2016 was $51.9 million, compared to $0.4 million for the same period in 2015. Other Income in the fourth quarter of 2016 includes $51.2 million from the M923 Asset Return and Termination Agreement with Baxalta, a wholly-owned subsidiary of Shire plc. The $51.2 million payment, received in January of 2017, is intended to fund Momenta's estimated costs of performing the development activities that would have been performed by Shire through the original termination date of September 27, 2017. For the full year 2016 Other Income was $53.7 million compared to $1.1 million in 2015.

At December 31, 2016, the Company had cash, cash equivalents, and marketable securities of $353.2 million compared to $350.0 million at December 31, 2015. The year-end cash balance excludes the receipt of a $51.2 million payment from Shire in January 2017 and a $50.0 million upfront payment from CSL that the Company expects to receive in the first quarter of 2017. Current cash balances are expected to be primarily used to fund the Company's pipeline, operations and research activities.

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 figures. 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 and collaboration expenses incurred by the Company that are reimbursable by Sandoz. Today, Momenta provided non-GAAP operating expense guidance of approximately $200 - $240 million for 2017. This guidance includes approximately $55 million of spending on M923 that will now be included in the Company's 2017 operating expenses. Of the $55 million, $51 million of the expense has already been paid by Shire as part of the termination agreement. Non-GAAP operating expense in the first quarter of 2017 is expected to be $50 - $60 million. The quarterly recognition of collaborative revenues under the Company's collaboration with Mylan is expected to be approximately $2.0 million per quarter. Based on the Asset Return and Termination Agreement with Baxalta, the Company recognized the full balance of its residual deferred revenues from that agreement in the fourth quarter of 2016 and will not recognize revenues from that agreement on a go-forward basis.

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 and excludes non-cash stock compensation expense and is net of collaborative reimbursement revenues from Sandoz. This non-GAAP financial measure should not be considered an alternative to GAAP total operating expense and should not be considered a measure of Momenta's liquidity. Non-GAAP financial measures should not be considered as substitutes for measures calculated in accordance with GAAP and should only be used to supplement an understanding of Momenta's operating results as reported under GAAP. Momenta has not provided a GAAP reconciliation for its forward-looking non-GAAP annual 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 anticipated reconciling information that is available without unreasonable effort in the section of this press release above entitled "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. 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 62528080. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through February 28, 2017. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 62528080.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for autoimmune indications.

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 the regulatory approval and launch of our product candidates, including Glatopa 40 mg; the Company's ability to meet its development and strategic goals; the dependence of an approval of the Glatopa 40 mg ANDA on resolution of the compliance observations in the FDA warning letter issued to Pfizer; expectations regarding long-term growth and sustainability; future operating expenses; program development and collaboration plans; timing of regulatory submissions; timing of clinical trials and the availability and announcement of clinical data; timing of patent litigation and other patent-related proceedings and decisions related to such litigation and proceedings; assessment of patents that are the subject of patent litigation; ability to generate value from our product candidates; and expectations regarding quarterly recognition of consideration and revenues under the Company's collaborations and how the Company plans to use its current cash balances. Forward-looking statements may be identified by words such as "believe," "continue," "could," "expect," "guidance," "may," "plan," "potential," "target," "will" 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, 2016, 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:
Sarah Carmody
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, 2016	December 31, 2015
Assets		
Cash, cash equivalents and marketable securities	$ 353,151	$ 350,044
Collaboration receivable	70,242	21,185
Restricted cash	21,761	20,660
Other assets	32,583	29,151
Total assets	$ 477,737	$ 421,040
Liabilities and Stockholders' Equity		
Current liabilities	$ 70,676	$ 38,782
Deferred revenue, net of current portion	31,360	12,213
Other long-term liabilities	3,793	69
Stockholders' equity	371,908	369,976
Total liabilities and stockholders' equity	$ 477,737	$ 421,040

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Statements of Operations and Comprehensive Income (Loss)

(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Collaboration revenues:				
Product revenue	$ 15,817	$ 17,810	$ 74,648	$ 48,503
Research and development revenue	18,378	4,583	34,971	41,147
Total collaboration revenue	34,195	22,393	109,619	89,650
Operating expenses:				
Research and development*	26,382	37,568	119,880	126,033
General and administrative*	18,165	14,373	64,466	48,051
Total operating expenses	44,547	51,941	184,346	174,084
Operating loss	(10,352)	(29,548)	(74,727)	(84,434)
Other income	51,891	384	53,724	1,121
Net income (loss)	$ 41,539	$ (29,164)	$ (21,003)	$ (83,313)
Basic net income (loss) per share	$ 0.60	$ (0.43)	$ (0.31)	$ (1.32)
Diluted net income (loss) per share	$ 0.60	$ (0.43)	$ (0.31)	$ (1.32)
Weighted average shares used in computing basic net income (loss) per share	69,003	68,138	68,656	63,130
Weighted average shares used in computing diluted net income (loss) per share	69,362	68,138	68,656	63,130
Comprehensive income (loss)	$ 41,375	$ (29,176)	$ (20,921)	$ (83,293)

* Non-cash share-based compensation expense included in operating expenses is as follows:

Research and development	$ 1,132	$ 2,114	$ 7,558	$ 5,145
General and administrative	$ 2,434	$ 2,539	$ 10,764	$ 6,295