May 2, 2017

# Momenta Pharmaceuticals Reports First Quarter 2017 Financial Results

*--Company reports Glatopa® 20 mg product revenues of $23 million, a 58% increase over the same period in 2016--*

*--Ended the first quarter with a strong cash position of $434 million--*

CAMBRIDGE, Mass., May 02, 2017 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the first quarter ended March 31, 2017.

"We continue to demonstrate the value of our Glatopa business both with increased revenues year-over-year for the 20 mg product and the potential of the 40 mg product to be launched this year," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Our biosimilar and novel autoimmune programs also showed strong momentum. We expect to submit our biosimilar HUMIRA® candidate for marketing approval mid-year followed by Phase 1 top-line data for our biosimilar ORENCIA® candidate, in collaboration with Mylan. For our novel autoimmune programs, data from the M281 Phase 1 study is expected in the second half of the year and we expect our lead program with CSL, M230, to enter the clinic this year."

**First Quarter Highlights and Recent Events**

**Complex Generics:**

**Glatopa 20 mg:** First FDA-approved, substitutable generic daily COPAXONE® 20 mg (glatiramer acetate injection) for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz.

- In the first quarter of 2017, Momenta recorded $23.4 million in product revenues from Sandoz's Glatopa 20 mg sales compared to $14.8 million in the same period in 2016.

**Glatopa 40 mg:** Designed to be a generic version of three-times-a-week COPAXONE 40 mg for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz.

- The Abbreviated New Drug Application (ANDA) submitted by Sandoz is under U.S. Food and Drug Administration (FDA) review. On February 17, 2017, the Company announced that Sandoz's contracted fill/finish manufacturing partner for Glatopa, Pfizer, received an FDA warning letter. 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. Pfizer submitted a comprehensive response to the observations cited in the warning letter. The Company believes that an approval from the FDA continues to be possible in 2017.
- On January 30, 2017, the U.S. District Court of Delaware found four of Teva Pharmaceutical's U.S. Orange Book listed patents for COPAXONE 40 mg to be invalid due to obviousness. On February 2, 2017, Teva filed a notice of appeal of the decision to the U.S. Court of Appeals for the Federal Circuit (CAFC). The Company expects a decision from the CAFC in late 2017 or early 2018.
- 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 April 23, 2017, the parties filed a joint motion to dismiss the suit for the '874 patent.

**Biosimilars:**

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

- In January, the Company received a one-time asset return payment of $51.2 million from Baxalta, a wholly-owned subsidiary of Shire plc, for the early termination of the M923 collaboration agreement.
- 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 the 2020

timeframe.

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

- In April 2017, the Phase 1 clinical trial for M834 completed enrollment. The companies plan to report top-line data from the Phase 1 trial in the second half of 2017.
- 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 product following the Company's Inter Partes Review challenging this patent. The Company has appealed the decision to the CAFC and expects a decision in April 2018. A motion to dismiss the appeal is pending.

**M710:** a biosimilar candidate being developed in collaboration with Mylan

- The companies continue to progress M710 and expect to initiate a clinical trial for this program in late 2017, or early 2018.

**Novel Drugs for Autoimmune Indications:**

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

- In January 2017, the Company initiated the multiple ascending dose portion of the Phase 1 study in healthy volunteers. To date no serious adverse events have been observed. 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.

**M230 (SIF3):** a Selective Immunomodulator of Fc receptors

- On January 5, 2017, the Company announced that it 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.
- On February 17, 2017 the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act) in connection with the license agreement and research collaboration with CSL expired. Momenta received a $50 million upfront cash payment from CSL in March 2017.

**M254 (hsIVIg):** a robust, controlled sialylation process to generate tetra-Fc-sialylated immunoglobulins with consistent enhanced anti-inflammatory activity

- The Company continues to progress the M254 program and expects to initiate an IND-enabling toxicology study in 2017 and is targeting a clinical trial in 2018.

**First Quarter 2017 Financial Results**

**Revenue:** In the first quarter of 2017, the Company recorded $23.4 million in product revenues from Sandoz's sales of Glatopa 20 mg, compared to $14.8 million for the same period in 2016. The increase in product revenues of $8.6 million, or 58%, was primarily due to a higher number of Glatopa 20 mg units sold. Collaborative research and development revenue for the first quarter of 2017 was $3.2 million compared to $5.1 million recorded in the same quarter last year. The decrease in research and development revenue of $1.9 million, or 37%, was primarily due to the termination of the Baxalta Collaboration Agreement, effective December 31, 2016, under which the Company was reimbursed for M923 employee expenses and external costs and for which the Company recognized a portion of Baxalta's initial upfront payment in the first quarter of 2016. Total revenues for the first quarter of 2017 were $26.6 million compared to $19.9 million for the same period in 2016.

**Operating Expenses:** Total GAAP operating expenses were $59.2 million in the first quarter of 2017. Research and development expenses for the first quarter of 2017 were $36.1 million, compared to $28.8 million for the same period in 2016. The increase of $7.3 million, or 25%, was primarily due to increased spending on M923 as the program was transitioned back to the Company effective December 31, 2016, as a result of the termination of the Baxalta Collaboration Agreement.

General and administrative expenses for the first quarter of 2017 were $23.1 million, compared with $15.6 million for the same period in 2016. The increase of $7.5 million, or 48%, was primarily driven by increases of $5.0 million relating to the Company's ongoing litigation and $2.0 million in personnel-related expenses, of which $1.6 million represents share-based compensation expense.

First quarter non-GAAP operating expense was $51.0 million, in line with previously provided guidance of $50 - $60 million per quarter in 2017.

**Net Loss:** The Company reported a net loss of $31.8 million, or $0.46 per share for the first quarter of 2017 compared to a net loss of $24.0 million, or $0.35 per share for the same period in 2016.

**Cash Position:** At March 31, 2017, Momenta had $433.7 million in cash, cash equivalents and marketable securities compared to $353.2 million at December 31, 2016. Cash provided by operating activities was $63.0 million during the first quarter of 2017, driven by the receipt of $51.2 million from the termination of the Baxalta Collaboration Agreement and the $50.0 million upfront payment from CSL pursuant to the worldwide license agreement, as compared to approximately $13.9 million during the first quarter of 2016.

In April 2015, Momenta entered into an ATM agreement with Stifel under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $75 million. In the first quarter of 2017, the Company recorded net proceeds of $18.5 million, of which $4.1 million was received in April 2017, from the sale of 1.3 million shares of common stock sold through the ATM agreement.

**2017 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 is reiterating non-GAAP operating expense guidance of approximately $200 - $240 million for 2017 and $50 - $60 million for the second quarter of 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. The quarterly recognition of collaborative revenues under the Company's collaboration with Mylan is expected to be approximately $1.8 million per quarter. The Company expects to recognize the $50 million upfront payment from CSL as revenue in the second half of 2017.

**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 "2017 Financial Guidance."

**Conference Call Information**

Management will host a conference call and webcast today at 10:00 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 9265541. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through May 9, 2017. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 9265541.

**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 our regulatory filings seeking marketing approval; the timing of 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; 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; expectations regarding accounting treatment for and recognition of consideration and revenues under the Company's collaborations and how the Company plans to use its current cash balances; reconciling information; non-GAAP operating expense guidance; utilization of the April 2015 ATM facility; and interchangeable biologics. Forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "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 Annual Report on Form 10-K for the year ended December 31, 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.

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

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 433,749 | $ 353,151 |
| Collaboration receivable | 26,544 | 70,242 |
| Restricted cash | 21,761 | 21,761 |
| Other assets | 37,360 | 32,583 |
| Total assets | $ 519,414 | $ 477,737 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | $ 114,486 | $ 70,676 |
| Deferred revenue, net of current portion | 29,653 | 31,360 |
| Other long-term liabilities | 4,960 | 3,793 |
| Stockholder's equity | 370,315 | 371,908 |
| Total liabilities and stockholders' equity | $ 519,414 | $ 477,737 |

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

| | Three Months Ended |
|---|---|

| | March 31, | |
|---|---|---|
| | 2017 | 2016 |
| Collaboration revenues: | | |
| Product revenue | $ 23,404 | $ 14,800 |
| Research and development revenue | 3,210 | 5,050 |
| Total collaboration revenue | 26,614 | 19,850 |
| | | |
| Operating expenses: | | |
| Research and development* | 36,101 | 28,757 |
| General and administrative* | 23,105 | 15,647 |
| Total operating expenses | 59,206 | 44,404 |
| | | |
| Operating loss | (32,592) | (24,554) |
| | | |
| Other income | 833 | 542 |
| | | |
| Net loss | $ (31,759) | $ (24,012) |
| | | |
| Basic and diluted net loss per share | $ (0.46) | $ (0.35) |
| | | |
| Weighted average shares used in computing basic and diluted net loss per share | 69,711 | 68,285 |

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

| | | |
|---|---|---|
| Research and development | $ 2,463 | $ 2,065 |
| General and administrative | $ 4,340 | $ 2,763 |


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