



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

August 9, 2018

CAMBRIDGE, Mass., Aug. 09, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the second quarter ended June 30, 2018 and provided a corporate update.

"The strategic review of our business announced earlier this year is progressing and we are actively evaluating options for our biosimilars business. We expect to complete this review and announce an outcome in the coming weeks," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Our novel drug candidates for rare autoimmune diseases continue to advance. We remain on track to initiate two Phase 2 proof of concept studies of M281 in the fourth quarter of 2018 and a Phase 1/2 proof of concept study of M254, our hyper-sialylated IVIg candidate, in late 2018 or early 2019, pending regulatory feedback."

Second Quarter 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 second quarter of 2018, Momenta recorded \$11.8 million in product revenues from Sandoz's sales of Glatopa 20 mg/mL and 40 mg/mL products.

Enoxaparin Sodium Injection: First FDA-approved, substitutable generic LOVENOX® (Enoxaparin Sodium Injection) used for the prevention and treatment of deep vein thrombosis developed in collaboration with Sandoz

- In June 2018, Sandoz alerted its customers and the U.S. Food and Drug Administration (FDA) that it will be discontinuing the supply of the Enoxaparin Sodium Injection product.

Biosimilars:

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

- In January 2018, the Company announced that the Biologics License Application (BLA) for M923 is prepared to be filed with the FDA.
- In June 2018, Momenta announced that it had reached a contract amendment to an agreement with Human Genome Sciences, Inc. ("GSK"), the supplier of product for M923, in which Momenta will pay GSK \$15.0 million by August 15, 2018 and \$15.0 million by July 1, 2019 as part of Momenta's contractual commitments for the purchase of product batches for M923 through 2022.

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

- In late 2017, Momenta announced that M834 did not meet its primary pharmacokinetic endpoints in a Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834 to US- and EU-sourced ORENCIA in normal healthy volunteers. Momenta and Mylan continue to investigate these results in order to determine the next steps for the program.

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

- In January 2018, Momenta and Mylan disclosed that M710 is a proposed biosimilar to EYLEA and announced an IND acceptance by the FDA. The two companies are in the process of initiating the pivotal clinical trial in patients and the trial is progressing according to plan.

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)

- Momenta is finalizing its development strategy for M281 and planning two Phase 2 proof of concept clinical trials in the fourth quarter of 2018, pending regulatory feedback.

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 (hslIVIg): 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 has successfully completed the IND-enabling toxicology study of M254 and is targeting the initiation of a Phase 1/2 proof of concept study in late 2018 or early 2019, pending regulatory feedback.

Second Quarter 2018 Financial Results

Revenue: In the second quarter of 2018, the Company recorded \$11.8 million in product revenues from Sandoz's sales of Glatopa 20 mg/mL and 40 mg/mL products compared to \$19.1 million in profit share from Sandoz sales of Glatopa 20 mg/mL for the same period in 2017, net of a deduction of \$0.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses. The decrease in product revenues of \$7.3 million, or 38%, was primarily due to lower net sales driven by market decline and Mylan N.V.'s entry into the COPAXONE market.

Research and development revenue for the second quarter of 2018 was \$1.3 million compared to \$4.4 million recorded in the same quarter last year. The decrease in research and development revenue of \$3.1 million, or 70%, was primarily due to lower revenue recognized from the Mylan upfront payment as compared to the amount recognized in the 2017 period and lower reimbursable expenses for the Company's complex generic programs.

Total revenues for the second quarter of 2018 were \$13.0 million compared to \$23.6 million for the same period in 2017.

Operating Expenses: Total GAAP operating expenses were \$83.9 million in the second quarter of 2018.

Research and development expenses for the second quarter of 2018 were \$31.3 million, compared to \$39.1 million for the same period in 2017. The decrease of \$7.8 million, or 20%, 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 second quarter of 2018 were \$22.5 million, compared with \$22.6 million for the same period in 2017.

During the second quarter, Momenta entered into a contract amendment to an agreement with GSK, the supplier of product for M923, for which Momenta will pay GSK \$30.0 million as part of Momenta's contractual commitments for the purchase of product batches for M923 through 2022. The amount has been included in operating expenses for the quarter. As a result, second quarter non-GAAP operating expense was \$78.0 million. Excluding the expense associated with the amendment of the M923 agreement, non-GAAP operating expense would be \$48.0 million. Momenta previously provided guidance of \$45 - \$55 million for non-GAAP operating expense for the second quarter. Non-GAAP operating expense is total operating expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense 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 \$69.9 million, or \$0.91 per share for the second quarter of 2018 compared to a net loss of \$36.9 million, or \$0.50 per share for the same period in 2017.

Cash Position: At June 30, 2018, Momenta had \$321.2 million in cash, cash equivalents and marketable securities compared to \$346.0 million at March 31, 2018.

2018 Financial Guidance

Due to the ongoing strategic review of the business, Momenta's 2018 operating expense guidance is no longer accurate and may continue to change subject to the outcome of the Company's strategic review. Momenta plans to provide updated 2018 operating expense guidance for 2018 when it reports its third quarter 2018 financial results.

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 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 8687156. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible

through August 16, 2018. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 8687156.

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.

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 the status and timing and/or substance of the outcome of 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 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; 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. 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)

| | June 30, 2018 | December 31, 2017 |
|--|---------------|-------------------|
| Assets | | |
| Cash, cash equivalents and marketable securities | \$ 321,197 | \$ 379,890 |
| Collaboration receivable | 13,229 | 15,048 |
| Restricted cash | 20,620 | 23,032 |
| Other assets | 40,414 | 41,461 |
| Total assets | \$ 395,460 | \$ 459,431 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | \$ 49,407 | \$ 44,487 |
| Deferred revenue, net of current portion | 34,394 | 30,751 |
| Other long-term liabilities | 29,968 | 10,039 |
| Stockholder's equity | 281,691 | 374,154 |
| Total liabilities and stockholders' equity | \$ 395,460 | \$ 459,431 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|-------------------------|-----------------------------|-----------|---------------------------|-----------|
| | 2018 | 2017 | 2018 | 2017 |
| Collaboration revenues: | | | | |
| Product revenue | \$ 11,779 | \$ 19,140 | \$ 15,300 | \$ 42,544 |

| | | | | |
|---|--------------|--------------|---------------|--------------|
| Research and development revenue | 1,252 | 4,430 | 2,583 | 7,640 |
| Total collaboration revenue | 13,031 | 23,570 | 17,883 | 50,184 |
| Operating expenses: | | | | |
| Research and development | 31,340 | 39,063 | 64,582 | 75,164 |
| General and administrative | 22,531 | 22,572 | 43,143 | 45,677 |
| Other | 30,000 | - | 30,000 | - |
| Total operating expenses | 83,871 | 61,635 | 137,725 | 120,841 |
| Loss from operations | (70,840) | (38,065) | (119,842) | (70,657) |
| Other income, net | 955 | 1,157 | 2,326 | 1,990 |
| Net loss | \$ (69,885) | \$ (36,908) | \$ (117,516) | \$ (68,667) |
| Net loss per share: | | | | |
| Basic and diluted | \$ (0.91) | \$ (0.50) | \$ (1.55) | \$ (0.96) |
| Shares used in calculating net loss per share | | | | |
| Basic and diluted | 76,543 | 73,379 | 76,002 | 71,555 |
| Comprehensive loss | \$ (69,611) | \$ (36,933) | \$ (117,677) | \$ (68,758) |

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 June 30, | | Six Months Ended June 30, | |
|---|------------------------------------|-------------|----------------------------------|-------------|
| | 2018 | 2017 | 2018 | 2017 |
| GAAP operating expenses | \$ 83,871 | \$ 61,635 | \$ 137,725 | \$ 120,841 |
| Adjustments: | | | | |
| Non-cash stock compensation expense | (5,172) | (4,590) | (10,046) | (11,393) |
| Collaboration expenses that are recorded as revenue and are reimbursable by collaborators | (735) | (3,049) | (1,318) | (4,463) |
| Non-GAAP operating expenses | \$ 77,964 | \$ 53,996 | \$ 126,361 | \$ 104,985 |

 [Primary Logo](#)

Source: Momenta Pharmaceuticals, Inc.