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

May 8, 2018

CAMBRIDGE, Mass., May 08, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the first quarter ended March 31, 2018 and provided a corporate update.

“We made important progress in the first quarter of 2018 across our complex generic, biosimilar and novel drug portfolios. Importantly, Glatopa 40 mg/mL received FDA approval and, with Sandoz’s commercial launch now underway, we look forward to the potential for accelerated adoption by customers as the year progresses. In addition, we are looking forward to the start-up of the pivotal patient trial for M710, our proposed biosimilar to EYLEA® being developed in collaboration with Mylan, in the first half of 2018,” said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. “Our novel drug portfolio targeted at rare autoimmune indications also continues to advance. Earlier this year, we announced positive topline data from the Phase 1 study of M281, our potentially best-in-class anti-FcRn candidate; and CSL’s initiation of a Phase 1 study of M230, our potential first-in-class recombinant Fc multimer. M254, our hyper-sialylated IVIg, also remains on track to enter a Phase 1 study this year.”

Wheeler continued, “The strategic review of our business announced earlier this year is active and we are evaluating options for our business including the potential for new partnerships across the portfolio or the sale of one or more of our biosimilar assets. We expect to complete this strategic review by the end of the second quarter of 2018.”

First 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

- On February 13, 2018, Momenta announced that the FDA had approved Sandoz's Abbreviated New Drug Application for Glatopa 40 mg/mL and that Sandoz initiated the launch of the product in the US. Sandoz has secured customer contracts and orders of Glatopa 40 mg/mL have been shipped. Sandoz had to build inventory of Glatopa 40 mg/mL for the US launch and expects accelerated adoption by customers as the year progresses.
- In the first quarter of 2018, Momenta recorded $3.5 million in product revenues from Sandoz’s sales of Glatopa 20 mg/mL and 40 mg/mL products, reflecting $13.3 million in profit share, net a deduction of $9.8 million in the first quarter of 2018 for 50% of Glatopa 40 mg/mL inventory reserves.

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

- On March 20, 2018, the US District Court of Massachusetts issued its final judgment affirming its February 2018 decision in the Company’s patent litigation against Amphastar involving US Patent No. 7,575,886, covering methods for the manufacturing control of generic LOVENOX, finding that the Company’s ‘886 patent was infringed by two separate methods used by Amphastar, but invalid for lack of written description and enablement. Momenta and Sandoz have appealed the case to the Court of Appeals for the Federal Circuit. Amphastar has moved to seek damages under the bond posted in connection with the preliminary injunction granted in 2010. Momenta and Sandoz have opposed the motion as premature pending a final ruling on appeal.
- On March 20, 2018, the US District Court of Massachusetts also denied Momenta and Sandoz’s motion to dismiss Amphastar’s antitrust lawsuit. A trial is scheduled for September 2019. Momenta has filed a motion to certify the denial of the motion to dismiss as eligible for interlocutory appeal on the grounds that dismissal is warranted under law and an appeal at this time could resolve the case.

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. The timing of Momenta’s filing of the BLA is dependent on the outcome of the Company’s ongoing strategic review.

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® (aflibercept) candidate being developed in collaboration with Mylan

- In January 2018, Momenta and Mylan disclosed that M710 is a proposed biosimilar to EYLEA and announced IND acceptance by the FDA. The companies plan to start-up the pivotal clinical trial in patients in the first half of 2018.

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)

- In January 2018, the Company reported positive top-line data showing safety, tolerability and proof of mechanism for M281 in a Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study in normal human volunteers. Over the 98-day MAD study, M281 exhibited no serious adverse events, was well tolerated, and decreased circulating IgG levels up to 89% with a mean reduction of 84%.
- Momenta is finalizing its development strategy for M281 and is planning two proof of concept clinical trials in the second half of 2018, pending regulatory feedback.

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

- In late January 2018, CSL began dosing subjects in the Phase 1 trial in healthy volunteers to evaluate the safety and tolerability of M230. The Phase 1 study is targeted to be completed in 2019.

M254 (hsIVIg): 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 is on track to complete the IND-enabling toxicology study this year and is targeting the initiation of a clinical trial in the second half of 2018.

First Quarter 2018 Financial Results

Revenue: In the first quarter of 2018, the Company recorded $3.5 million in product revenues from Sandoz's sales of Glatopa 20 mg/mL and 40 mg/mL products reflecting $13.3 million in profit share, net a deduction of $9.8 million for 50% of Glatopa 40 mg/mL inventory reserved by Sandoz, compared to $23.4 million in profit share from Sandoz sales of Glatopa 20 mg/mL for the same period in 2017. The decrease in product revenues of $19.9 million, or 85%, was primarily due to lower net sales driven by market decline, Mylan N.V.'s entry into the COPAXONE market, and Glatopa 40 mg/mL pre-launch inventory reserves.

Research and development revenue for the first quarter of 2018 was $1.3 million compared to $3.2 million recorded in the same quarter last year. The decrease in research and development revenue of $1.9 million, or 59%, 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 first quarter of 2018 were $4.9 million compared to $26.6 million for the same period in 2017.

Operating Expenses: Total GAAP operating expenses were $53.9 million in the first quarter of 2018.

Research and development expenses for the first quarter of 2018 were $33.2 million, compared to $36.1 million for the same period in 2017. The decrease of $2.9 million, or 8%, was primarily due to a decrease in external R&D expenses for M923 offset by increases in spending for M710 and M281.

General and administrative expenses for the first quarter of 2018 were $20.6 million, compared with $23.1 million for the same period in 2017. The decrease of $2.5 million, or 11%, was primarily driven by lower legal expenses related to the Company's litigation.

First quarter non-GAAP operating expense was $48.4 million, within the range of previously provided guidance of $45 - $55 million. 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 $47.6 million, or $0.63 per share for the first quarter of 2018 compared to a net loss of $31.8 million, or $0.46 per share for the same period in 2017.

Cash Position: At March 31, 2018, Momenta had $346.0 million in cash, cash equivalents and marketable securities compared to $379.9 million at December 31, 2017.

2018 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 expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense and collaborative reimbursement revenues. Today, Momenta is reiterating non-GAAP operating expense guidance of approximately $180 - $220 million for 2018 and $45 - $55 million for the second quarter of 2018. The Company expects to continue to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. The Company also estimates that collaborative reimbursement revenues will be approximately $0 - $2 million per quarter in 2018. The Company's guidance for 2018 is subject to potential changes in operating plans based on the outcome of the strategic review.

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 7665388. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through 7665388. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 7665388.

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 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, including next steps for M834; 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 40 mg profits; 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; our strategic business review and 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 Annual Report on Form 10-K for the year ended December 31, 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.

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

	March 31, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 346,008	$ 379,890
Collaboration receivable	4,753	15,048
Restricted cash	23,032	23,032
Other assets	43,151	41,461
Total assets	$ 416,944	$ 459,431
Liabilities and Stockholders’ Equity		
Current liabilities	$ 34,512	$ 44,487
Deferred revenue, net of current portion	34,890	30,751
Other long-term liabilities	13,125	10,039
Stockholder's equity	334,417	374,154
Total liabilities and stockholders’ equity	$ 416,944	$ 459,431

MOMENTA PHARMACEUTICALS, INC.

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

	Three Months Ended March 31, 2018	2017
Collaboration revenues:		
Product revenue	$ 3,521	$ 23,404
Research and development revenue	1,331	3,210
Total collaboration revenue	4,852	26,614
Operating expenses:		
Research and development	33,242	36,101
General and administrative	20,612	23,105
Total operating expenses	53,854	59,206
Loss from operations	(49,002)	(32,592)
Other income, net	1,371	833
Net loss	$ (47,631)	$ (31,759)
Net loss per share:		
Basic and diluted	$ (0.63)	$ (0.46)
Shares used in calculating net loss per share		
Basic and diluted	75,454	69,711
Comprehensive loss	$ (48,066)	$ (31,825)

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 March 31, 2018	2017
GAAP operating expenses	$ 53,854	$ 59,206
Adjustments:		
Non-cash stock compensation expense	(4,874)	(6,803)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(583)	(1,415)
Non-GAAP operating expenses	$ 48,397	$ 50,988

Primary Logo

Source: Momenta Pharmaceuticals, Inc.