August 2, 2017

Momenta Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Corporate Update

$10M milestone payment from Sandoz earned for the second anniversary of Glatopa® 20 mg as the sole FDA-approved generic on the market for patients with relapsing forms of multiple sclerosis

Ended second quarter with a strong cash position of $457M

CAMBRIDGE, Mass., Aug. 02, 2017 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the second quarter ended June 30, 2017 and provided a corporate update.

"In the second quarter Glatopa 20 mg continued to provide us with steady funding and recently earned us a $10 million milestone payment from Sandoz for its continued success as the sole FDA-approved generic version of COPAXONE® on the market. We remain optimistic that we could see a potential Glatopa 40 mg approval and launch into the marketplace in the 2017 timeframe," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Our biosimilar programs also continue to advance with several anticipated events later this year including a potential submission for marketing approval of our biosimilar HUMIRA® candidate, and with our collaboration partner Mylan, top-line data from our biosimilar ORENCIA® candidate and progressing M710 toward a clinical trial. For our novel drugs, we look forward to working with CSL to advance M230 into the clinic and reporting data for our wholly-owned asset M281."

Second 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 second quarter of 2017, Momenta recorded $19.1 million in product revenues from Sandoz's Glatopa 20 mg sales, net a deduction of $0.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $20.7 million in the same period in 2016.
- On July 1, 2017, Momenta earned a $10 million milestone payment from Sandoz in connection with Glatopa 20 mg continuing to be the sole FDA-approved generic of COPAXONE 20 mg and achieving a certain level of contractually defined profits in the U.S. two years following its launch.

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. An approval of the application may be dependent on the satisfactory resolution of the compliance observations stated in the FDA warning letter issued in February 2017 to Pfizer, the contracted fill/finish manufacturing partner for Glatopa. Pfizer has 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.

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 July 21, 2017, the jury in the U.S. District Court of Massachusetts in Boston issued its verdict finding that the Company's U.S. Patent No. 7,575,886, covering methods for the manufacturing control of generic LOVENOX, was infringed by Amphastar, but invalid and unenforceable. The Company is considering all available legal options to overturn the verdict, including post-trial motions and appeals. Final judgment has not yet been entered.

Biosimilars:

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

- Momenta is working toward the first submission for marketing approval of M923 in the fourth quarter of 2017. The Company is preparing for a first commercial launch of M923 as early as the 2020 timeframe, subject to marketing approval and patent considerations.

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 appealed the decision to the CAFC, and in June 2017 a motion filed by Bristol Myers Squibb to dismiss the Company's appeal was denied. The Court has expedited the appeal process providing the potential for a hearing in the fourth quarter of 2017.

M710: a biosimilar candidate being developed in collaboration with Mylan

- The companies continue to progress M710 and are targeting a first regulatory submission for clinical development 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)

- The Company expects to complete the multiple ascending dose portion of the Phase 1 study in healthy volunteers in August 2017. To date no serious adverse events have been observed. The Company plans to report the 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 being developed in collaboration with CSL

- Momenta and CSL have agreed upon a development plan for M230 which is expected to enter the clinic in 2017.
- Under the agreement with CSL, Momenta has the option to elect a 50% cost and profit sharing arrangement for M230, for which Momenta would fund 50% of global research and development and U.S. commercialization and manufacturing costs in exchange for 50% of U.S. profits, plus milestones and royalties outside the United States. The Company is required to make its decision on the 50% cost and profit sharing option in the third quarter of 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.

Second Quarter 2017 Financial Results

Revenue: In the second quarter of 2017, the Company recorded $19.1 million in product revenues from Sandoz's sales of Glatopa 20 mg, net a deduction of $0.6 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $20.7 million for the same period in 2016. The decrease in product revenues of $1.6 million, or 8%, was primarily due to lower sales deductions in the second quarter of 2016, as well as legal reimbursement in the second quarter of 2017. Research and development revenue for the second quarter of 2017 was $4.4 million compared to $5.7 million recorded in the same quarter last year. The decrease in research and development revenue of $1.3 million, or 23%, 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 second quarter of 2016. Total revenues for the second quarter of 2017 were $23.5 million compared to $26.4 million for the same period in 2016.

Operating Expenses: Total GAAP operating expenses were $61.6 million in the second quarter of 2017. Research and development expenses for the second quarter of 2017 were $39.1 million, compared to $33.2 million for the same period in 2016. The increase of $5.9 million, or 18%, was primarily due to $13.0 million in increased spending on M923, partially offset by a $2.2 million reduction in spend on necuparanib, which was discontinued in 2016, and a $3.5 million reduction in

R&D expenses for reimbursable M230 material costs incurred under the CSL License Agreement.

General and administrative expenses for the second quarter of 2017 were $22.6 million, compared with $14.9 million for the same period in 2016. The increase of $7.7 million, or 52%, was primarily driven by approximately $5.0 million of legal fees relating to the Company's ongoing litigation and $1.3 million in personnel-related expenses driven by increased headcount and higher share-based compensation expense.

Second quarter non-GAAP operating expense was $54.0 million, in line with previously provided guidance of $50 - $60 million per quarter in 2017. See 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 $36.9 million, or $0.50 per share for the second quarter of 2017 compared to a net loss of $21.0 million, or $0.31 per share for the same period in 2016.

Cash Position: At June 30, 2017, Momenta had $456.8 million in cash, cash equivalents and marketable securities compared to $433.7 million at March 31, 2017. During the second quarter of 2017 the Company received net proceeds of $49.6 million from the sale of 3.5 million shares of common stock, completing sales under the 2015 ATM agreement with Stifel.

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 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 collaboration expenses incurred by the Company that are reimbursable by collaborative partners. Today, Momenta is providing updated non-GAAP operating expense guidance of approximately $210 - $230 million for 2017 and $50 - $60 million for the third quarter of 2017. The annual guidance includes approximately $55 million of spending on M923 that, as a result of Shire's termination of the Baxalta collaboration agreement, 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 Company continues to expect to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. The Company also expects to recognize the $10 million Glatopa 20 mg milestone as revenue in the third quarter of 2017 and the $50 million upfront payment from CSL as revenue in the fourth quarter 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 as it excludes non-cash stock compensation expense and collaboration expenses incurred by the Company that are reimbursable by collaborative partners. 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 a 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 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 48279630. A replay of the call will be available approximately two hours

after the conclusion of the call and will be accessible through August 9, 2017. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 48279630.

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 for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates, including Glatopa 40 mg; development timelines; 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; timing of clinical trials and the timing, availability and announcement of data and results; timing of patent litigation and other patent-related proceedings and decisions related to such litigation and proceedings; the timing of the CSL cost and profit sharing arrangement opt-in; expectations regarding accounting treatment for and recognition of consideration and revenues under the Company's collaborations; reconciling information; non-GAAP operating expense guidance; and anticipated spend on M923 and its inclusion in operating expenses. Forward-looking statements may be identified by words and phrases such as "advance," "anticipate," 'being developed," "believe," "continue," "could," "expect," "guidance," "is required," "look forward to," "may," "plan," "potential," "preparing," "progress," "propose," "remain optimistic," "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 March 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.

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	$ 456,824	$ 353,151
Collaboration receivable	24,806	70,242
Restricted cash	21,761	21,761
Other assets	37,415	32,583
Total assets	$ 540,806	$ 477,737
Liabilities and Stockholders' Equity		
Current liabilities	$ 118,056	$ 70,676
Deferred revenue, net of current portion	30,761	31,360
Other long-term liabilities	5,128	3,793
Stockholder's equity	386,861	371,908
Total liabilities and stockholders' equity	$ 540,806	$ 477,737

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,	
	2017	**2016**	**2017**	**2016**
Collaboration revenues:				
Product revenue	$ 19,140	$ 20,692	$ 42,544	$ 35,492
Research and development revenue	4,430	5,738	7,640	10,788
Total collaboration revenue	23,570	26,430	50,184	46,280
Operating expenses:				
Research and development	39,063	33,173	75,164	61,930
General and administrative	22,572	14,896	45,677	30,543
Total operating expenses	61,635	48,069	120,841	92,473
Operating loss	(38,065)	(21,639)	(70,657)	(46,193)
Other income, net	1,157	653	1,990	1,195
Net loss	$ (36,908)	$ (20,986)	$ (68,667)	$ (44,998)
Net loss per share basic and diluted	$ (0.50)	$ (0.31)	$ (0.96)	$ (0.66)
Weighted average number of common shares used in net loss per share basic and diluted	73,379	68,532	71,555	68,409

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,	
	2017	**2016**	**2017**	**2016**
GAAP operating expenses	$ 61,635	$ 48,069	$ 120,841	$ 92,473
Adjustments:				
Non-cash stock compensation expense	(4,590)	(4,989)	(11,393)	(9,817)
Collaboration expenses that are reimbursable by collaborators	(3,049)	(1,453)	(4,463)	(3,139)
Non-GAAP operating expenses	$ 53,996	$ 41,627	$ 104,985	$ 79,517

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


Primary Logo

Source: Momenta Pharmaceuticals, Inc.

News Provided by Acquire Media