August 4, 2016

Momenta Pharmaceuticals Reports Second Quarter 2016 Financial Results

CAMBRIDGE, Mass., Aug. 04, 2016 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the second quarter ended June 30, 2016.

For the second quarter of 2016, the Company reported total revenues of $26.4 million, including $20.7 million in product revenues from Sandoz's sale of Glatopa® (glatiramer acetate injection). Momenta reported a net loss of $(21.0) million, or $(0.31) per share for the second quarter compared to a net loss of $(2.2) million, or $(0.04) per share for the same period in 2015. At June 30, 2016, the Company had cash, cash equivalents, and marketable securities of $336.9 million compared to $362.8 million at March 31, 2016.

"We are pleased with the growth in product revenues from Glatopa this quarter and look forward to the potential launch of our Glatopa 40 mg product next year," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "During the remainder of 2016 we plan to announce several key milestones including announcing top-line data from a pivotal trial for M923, a biosimilar candidate of HUMIRA® developed in collaboration with Baxalta, the initiation of a clinical trial for M834, a biosimilar candidate of ORENCIA® being developed in collaboration with Mylan, and completing enrollment of the single ascending dose portion of our Phase 1 trial for M281, a novel anti-FcRn antibody candidate."

Second Quarter Highlights and Recent Events

Complex Generics:

- In the second quarter of 2016, Momenta recorded $20.7 million in product revenues from Sandoz's Glatopa sales.
- The ANDA submitted by Sandoz for a three-times-a-week generic COPAXONE® 40 mg (glatiramer acetate injection) is under FDA review. The Company expects to receive tentative regulatory approval in 2016.
- A district court trial challenging four of Teva's five Orange Book-listed patents for COPAXONE 40 mg (glatiramer acetate injection) is scheduled for September 26, 2016.

Biosimilars:

- In April 2016, Momenta and its collaboration partner Baxalta, now a part of Shire, completed enrollment in the pivotal clinical trial for M923, a biosimilar candidate of HUMIRA® (adalimumab) and the companies expect to release results in late 2016. The companies are targeting first regulatory submission for marketing approval in 2017 and a first commercial launch as early as 2018.
- Momenta's global collaboration with Mylan to develop, manufacture and commercialize six of the Company's biosimilar candidates is progressing. The companies have prioritized three lead programs including M834, a biosimilar candidate of ORENCIA® (abatacept).

Novel Drugs:

Necuparanib (novel oncology candidate)

- On August 3, 2016, the Data Safety Management Board recommended that the Company discontinue further accrual in the Phase 2 trial of necuparanib in pancreatic cancer following the outcome of a planned interim futility analysis. The Company plans to confirm the futility analysis and then determine next steps for the necuparanib program.

Autoimmune Drugs

Momenta's novel autoimmune portfolio includes two recombinant molecules: M230, a Selective Immunomodulator of Fc receptors (SIF3) and M281, an anti-FcRn monoclonal antibody. In June 2016, the Company initiated a Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 in healthy subjects. M230 is in pre-clinical development, and the Company expects to initiate a clinical trial for M230 in 2017. Momenta is also developing

hyper-sialylated IVIg (hsIVIg), a high potency alternative to IVIg. The Company continues its efforts to identify potential collaboration opportunities for the further development and commercialization of its hsIVIg program.

Second Quarter 2016 Financial Results

Total revenues for the second quarter of 2016 were $26.4 million compared to $44.9 million for the same period in 2015. Total revenues for the second quarter of 2016 include $20.7 million in product revenue earned from net sales of Glatopa by Sandoz, compared to $19.2 million in product revenue earned from net sales of Glatopa by Sandoz for the same period in 2015. Glatopa was launched in the second quarter of 2015, and Glatopa profit share for that quarter was reduced by $9.0 million to reimburse Sandoz for the Company's share of pre-launch Glatopa-related legal expenses.

Collaborative research and development revenue for the second quarter of 2016 was $5.7 million compared to the $25.6 million recorded in the same quarter last year. In the second quarter of 2015, the Company earned $20.0 million in milestone payments under the Sandoz collaboration upon receiving sole FDA approval and upon the first commercial sale of Glatopa.

Research and development expenses for the second quarter of 2016 were $33.2 million, compared to $34.0 million for the same period in 2015. The decrease of $0.8 million, or 2%, from the 2015 period to the 2016 period was due to decreases of $0.8 million in stock-based compensation expense and $8.4 million for Mylan's 50% share of biosimilar collaboration costs, which was offset by increases of $4.4 million in process and clinical development costs for M281 and biosimilars under the Company's collaboration with Mylan, $2.2 million in non-clinical expenses to advance the Company's novel autoimmune programs, $1.0 million in personnel-related expenses and $0.7 million in necuparanib Phase 2 clinical trial costs.

General and administrative expenses for the quarter ended June 30, 2016 were $14.9 million, compared with $13.3 million for the same period in 2015. The increase of $1.6 million, or 12%, was primarily due to an increase of $2.1 million in legal and professional fees. This increase was offset by a decrease of $0.5 million for Mylan's 50% share of biosimilar collaboration costs.

At June 30, 2016, Momenta had $336.9 million in cash, cash equivalents and marketable securities.

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.

Today, Momenta reiterated its non-GAAP operating expense guidance of approximately $40 - $45 million per quarter for the second half of 2016. Non-GAAP operating expense is total operating expenses (which is net of Mylan's share of collaboration expenses), excluding stock-based compensation expense and net of collaborative reimbursement revenues from Sandoz and Baxalta. The quarterly recognition of collaborative revenues under the Company's collaborations with Baxalta and Mylan is expected to be $2.4 million and $1.8 million per quarter, respectively.

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 48928761. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through August 11, 2016. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 48928761.

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 and is net of collaborative reimbursement revenues from Sandoz and Baxalta. 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 2016 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 does not believe that such a reconciliation would be meaningful to stockholders.

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 oncology and 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 Company's ability to meet its development goals; expectations regarding long-term growth and sustainability; future operating expenses; program development and collaboration plans; timing of regulatory submissions, regulatory approvals and product launches; timing of completion of enrollment of the Company's clinical trials; 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; confirming the futility analysis of necuparanib; determining next steps for the necuparanib program and expectations regarding quarterly recognition of consideration under the Company's collaborations. Forward-looking statements may be identified by words such as "continue," "expect," "guidance," "look forward," "opportunity," "plan," "potential," "schedule," "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 March 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)

	June 30, 2016	December 31, 2015
Assets		
Cash, cash equivalents and marketable securities	$ 336,916	$ 350,044
Collaboration receivable	35,862	21,185
Restricted cash	20,660	20,660
Other assets	32,315	29,151
Total assets	$ 425,753	$ 421,040
Liabilities and Stockholders' Equity		
Current liabilities	$ 45,093	$ 38,782
Deferred revenue, net of current portion	42,189	12,213
Other long-term liabilities	3,832	69
Stockholders' equity	334,639	369,976
Total liabilities and stockholders' equity	$ 425,753	$ 421,040

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,	
	2016	**2015**	**2016**	**2015**
Collaboration revenues:				
Product revenue	$ 20,692	$ 19,305	$ 35,492	$ 22,027
Research and development revenue	5,738	25,595	10,788	31,436
Total collaboration revenue	26,430	44,900	46,280	53,463
Operating expenses:				
Research and development*	33,173	33,983	61,930	56,733
General and administrative*	14,896	13,329	30,543	21,219
Total operating expenses	48,069	47,312	92,473	77,952
Operating loss	(21,639)	(2,412)	(46,193)	(24,489)
Other income	653	190	1,195	390
Net loss	$ (20,986)	$ (2,222)	$ (44,998)	$ (24,099)
Basic and diluted net loss per share	$ (0.31)	$ (0.04)	$ (0.66)	$ (0.41)
Weighted average shares used in computing basic and diluted net loss per share	68,532	61,680	68,409	58,106
Comprehensive loss	$ (20,837)	$ (2,204)	$ (44,716)	$ (24,063)

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

Research and development	$ 2,319	$ 3,125	$ 4,384	$ 910
General and administrative	$ 2,670	$ 3,491	$ 5,433	$ 1,321

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

Source: Momenta Pharmaceuticals, Inc.

News Provided by Acquire Media