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Momenta Pharmaceuticals Reports First Quarter 2016 Financial Results

CAMBRIDGE, Mass., May 03, 2016 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the first quarter ended March 31, 2016.

For the first quarter of 2016, the Company reported total revenues of $19.9 million, including $14.8 million in product revenues from Sandoz's sale of Glatopa® (glatiramer acetate injection). Momenta reported a net loss of $(24.0) million, or $(0.35) per share for the first quarter compared to a net loss of $(21.9) million, or $(0.40) per share for the same period in 2015. At March 31, 2016, the Company had cash, cash equivalents, and marketable securities of $362.8 million compared to $350.0 million at December 31, 2015.

"Since the beginning of 2016, Momenta has made steady progress in each of our business areas," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Our biosimilars pipeline continues to advance. The pivotal trial for M923, our biosimilar version of HUMIRA® developed in collaboration with Baxalta, is now fully enrolled and our collaboration with Mylan for the development of six biosimilar candidates received HSR clearance and is progressing nicely. In our novel drug portfolio, our Phase 2 trial of necuparanib in patients with pancreatic cancer continues to enroll, and we remain on track for availability of top line data in the second half of 2017. We also received regulatory clearance to initiate a Phase 1 dosing study for M281, our novel anti-FcRn antibody, and anticipate dosing our first subject in the next several weeks.

"For the remainder of 2016, we look forward to continued progress across our pipeline of biosimilar and novel drug programs including the presentation of final Phase 1 results from our necuparanib trial and Phase 1 study of M923," continued Mr. Wheeler.

First Quarter Highlights and Recent Events

Complex Generics:

- In the first quarter of 2016, Momenta recorded $14.8 million in product revenues from Sandoz's Glatopa sales. Since the launch of Glatopa in June 2015, Momenta has recorded $58.2 million in product revenues from Sandoz's sales of Glatopa reflecting $67.3 million in profit share net of a deduction of $9.1 million for reimbursement to Sandoz of the Company's share of pre-launch Glatopa-related legal expenses.
- 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 Teva's four Orange Book-listed patents for COPAXONE 40 mg (glatiramer acetate injection) is scheduled for September 26, 2016.
- Momenta's product revenues from Sandoz's net sales of enoxaparin sodium injection decreased from $2.7 million in the first quarter of 2015 to zero for the same period in 2016.

Biosimilars:

- In April 2016, Momenta and Baxalta completed enrollment in the pivotal clinical trial for M923, a biosimilar candidate of HUMIRA® (adalimumab). The companies are targeting first regulatory submission in 2017 and a first commercial launch as early as 2018. The Company plans to present data from the pharmacokinetics study of M923 in a poster session at the European League against Rheumatism (EULAR) Annual Congress in London on June 10, 2016.
- In January 2016, Momenta announced a global collaboration with Mylan N.V. to develop, manufacture and commercialize six of the Company's biosimilar candidates, including M834, a biosimilar candidate of ORENCIA® (abatacept). On February 9, 2016, the companies received clearance for the collaboration under the Hart-Scott-Rodino Antitrust Improvements Act. In the first quarter of 2016 Momenta received an upfront cash payment of $45 million from Mylan.
- In January 2016, the U.S. Patent and Trademark Office (PTAB) instituted Momenta's request for an Inter Partes Review proceeding to challenge Bristol Myers Squibb's U.S. formulation Pat. 8,476,239 for ORENCIA. The Company

expects a decision from the PTAB in January 2017.

Novel Drugs:
Necuparanib (novel oncology candidate)

- Momenta's Phase 2 trial to evaluate the antitumor activity of necuparanib in combination with Abraxane® (nab-paclitaxel) plus gemcitabine, versus Abraxane plus gemcitabine alone, is enrolling. The Company expects to have clinical data in the second half of 2017.
- Momenta continues to collect data from the Phase 1 study of necuparanib and plans to present final data in a poster session at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in June 2016.

Autoimmune Drugs
Momenta's three novel autoimmune candidates are in preclinical development. These candidates include a hyper-sialylated IVIg (hsIVIg), a high potency alternative to IVIg, and two recombinant molecules: M230, a Selective Immunomodulator of Fc receptors (SIF3) and M281, an anti-FcRn monoclonal antibody. The Company is advancing the recombinant candidates with a goal of initiating clinical trials in 2016 for M281, and in 2017 for M230. The Company is continuing its efforts to identify and explore potential collaboration opportunities for the further development and commercialization of its hsIVIg program.

First Quarter 2016 Financial Results

Total revenues for the first quarter of 2016 were $19.9 million compared to $8.6 million for the same period in 2015. Total revenues for the first quarter of 2016 include $14.8 million in product revenue from Glatopa, which launched in June 2015, and no product revenue from enoxaparin, as no contractual profit was earned on Sandoz's net sales of enoxaparin for the quarter. Total revenue in the first quarter of 2015 included enoxaparin product revenue of $2.7 million. The decrease in enoxaparin product revenue is due to the change in collaboration economics from a royalty payment to 50% profit share, decreased unit sales due to lower market share and continued competitive pricing.

Collaborative research and development revenue for the first quarter of 2016 was $5.1 million compared to the $5.8 million recorded in the same quarter last year. In the first quarter of 2016, the Company received a $45.0 million upfront payment from Mylan. The upfront payment was allocated to the six products and will be recognized as revenue ratably over the estimated development periods of the six products in the collaboration. In the first quarter of 2016, $0.9 million of collaborative revenue from Mylan was recognized. The decrease in the balance of research and development revenue of $1.6 million from the 2015 period to the 2016 period is due primarily to lower reimbursable costs for M923, as Baxalta has assumed clinical development responsibility for that program.

The Company expects that collaborative research and development revenue earned by Momenta related to reimbursement from Baxalta and Sandoz will fluctuate from quarter to quarter in 2016 depending on research and development activities. The quarterly recognition of consideration under the Company's collaborations with Baxalta and Mylan is expected to be $2.4 million and $1.8 million per quarter, respectively.

Research and development expenses for the first quarter of 2016 were $28.8 million (net of $3.7 million reimbursable from Mylan), compared to $22.7 million for the same period in 2015. The increase of $6.1 million, or 27%, from the 2015 period was due to increases of $5.0 million in personnel-related expenses primarily attributed to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based stock awards, $3.3 million in third-party research and process development costs for the Company's biosimilar and novel autoimmune drug programs, $0.6 million of facility and depreciation expense, $0.6 million in necuparanib Phase 2 clinical trial expenses and $0.3 million in professional fees.

General and administrative expenses for the quarter ended March 31, 2016 were $15.6 million, compared with $7.9 million for the same period in 2015. The increase of $7.7 million, or 97%, was due to $6.3 million in personnel-related expenses primarily due to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based stock awards and a $1.4 million increase in professional fees.

At March 31, 2016, Momenta had $362.8 million in cash, cash equivalents and marketable securities.

Financial Guidance

The Company's guidance for the first quarter of 2016 for operating expenses, excluding stock-based compensation expense and net of collaborative reimbursement revenues from Sandoz and Baxalta, was $45 - $55 million. As shown in the table below, reported operating expenses, excluding stock-based compensation expense and net of collaborative reimbursement revenues from Sandoz and Baxalta, were $37.9 million. The guidance for the first quarter did not include consideration of the Mylan collaboration, in which the Company presents the cost sharing reimbursement from Mylan as a

reduction in operating expenses. Excluding the impact of the Mylan collaboration cost-sharing of $3.8 million, operating expenses were $41.7 million, as compared with guidance of $45 - $55 million. The lower expenses in the first quarter were primarily due to the timing of process development and manufacturing activities.

	Three Months Ended March 31,	
	2016	2015
Operating expenses:		
As reported	$ 44,404	$ 30,639
Share-based compensation (expense) income	(4,828)	4,385
Less: Collaborative reimbursement	(1,686)	(4,154)
Subtotal	37,890	30,870
Add: Mylan collaboration cost-sharing	3,792	—
	$ 41,682	$ 30,870

Today, Momenta provided guidance that it expects operating expenses (which will be reported net of Mylan's share of collaboration expenses), excluding stock-based compensation expense and net of collaborative reimbursement revenues from Sandoz and Baxalta, to be approximately $40 - $45 million per quarter for the remainder of 2016.

Conference Call Information

Management will host a conference call and webcast today at 9:00 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 and will be available for 90 days.

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 84504921. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through May 10, 2016. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 84504921.

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 for 2016; 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 clinical trials and the availability and announcement of clinical data; the timing of decisions related to patent litigation and other patent-related proceedings; expectations regarding collaborative research and development revenue earned by the Company; and expectations regarding quarterly amortization of consideration under the Company's collaborations. Forward-looking statements may be identified by words such as "continue," "target," "goal," "guidance," "plan," "potential," "estimate," "expect," "will," "look forward" 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, 2015, 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, 2016	December 31, 2015
Assets		
Cash and marketable securities	$ 362,828	$ 350,044
Collaboration receivable	21,742	21,185
Restricted cash	20,660	20,660
Other assets	30,193	29,151
Total assets	$ 435,423	$ 421,040
Liabilities and Stockholders' Equity		
Current liabilities	$ 36,873	$ 38,782
Deferred revenue, net of current portion	46,475	12,213
Other long-term liabilities	592	69
Stockholders' equity	351,483	369,976
Total liabilities and stockholders' equity	$ 435,423	$ 421,040

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

	Three Months Ended March 31,	
	2016	2015
Collaboration revenues:		
Product revenue	$ 14,800	$ 2,722
Research and development revenue	5,050	5,840
Total collaboration revenue	19,850	8,562
Operating expenses:		
Research and development*	28,757	22,749
General and administrative*	15,647	7,890
Total operating expenses	44,404	30,639
Operating loss	(24,554)	(22,077)
Other income:		
Interest income	480	112
Other income	62	88
Total other income	542	200
Net loss	$ (24,012)	$ (21,877)
Basic and diluted net loss per share	$ (0.35)	$ (0.40)
Weighted average shares used in computing basic and diluted net loss per share	68,285	54,492
Comprehensive loss:		
Net loss	$ (24,012)	$ (21,877)
Net unrealized holding gains (losses) on available-for-sale marketable securities	133	18
Comprehensive loss	$ (23,879)	$ (21,859)

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

Research and development	$ 2,065	$ (2,215)
General and administrative	$ 2,763	$ (2,170)

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