February 18, 2016

Momenta Pharmaceuticals Reports Fourth Quarter and Year End 2015 Financial Results

CAMBRIDGE, Mass., Feb. 18, 2016 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the fourth quarter and year ended December 31, 2015.

For the fourth quarter of 2015, the Company reported total revenues of $22.4 million, including $15.6 million in product revenues from Sandoz's sale of Glatopa® (glatiramer acetate injection). For the year ended December 31, 2015, the Company reported total revenues of $89.7 million, including $43.4 million in product revenues from Sandoz's sales of Glatopa and $20.0 million in milestone payments earned upon sole FDA approval and launch of Glatopa. Momenta reported a net loss of $(29.2) million, or $(0.43) per share for the fourth quarter compared to a net loss of $(16.0) million, or $(0.31) per share for the same period in 2014. For the year ended December 31, 2015, the Company reported a net loss of $(83.3) million, or $(1.32) per share compared to a net loss of $(98.6) million, or $(1.91) per share for the same period in 2014. At December 31, 2015, the Company had cash, cash equivalents, and marketable securities of $350.0 million compared to $191.5 million at December 31, 2014.

"The year 2015 proved to be pivotal in our company's growth and development. Glatopa, our second complex generic to receive FDA marketing approval, is the first and only substitutable generic product for multiple sclerosis on the market today. Glatopa's approval provided further validation of the strength of our proprietary analytic platform and physicochemical and biologic characterization capabilities, and has set the stage for our biosimilar and novel drug programs," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "In addition, Glatopa's approval allowed us to complete a successful financing that significantly strengthened our balance sheet and helped us secure a strong biosimilars collaboration partner in Mylan. We believe we are now well-positioned to execute on our biosimilar and novel drug programs in 2016 and to continue to build our business for long-term growth and sustainability."

Fourth Quarter Highlights and Recent Events

Complex Generics:

Glatopa®, generic version of daily COPAXONE® 20 mg (glatiramer acetate injection)

- In the fourth quarter of 2015, Momenta recorded $15.6 million in product revenues from Sandoz's Glatopa sales. Since the launch of Glatopa in June 2015, Momenta has recorded $43.4 million in product revenues from Sandoz's sales of Glatopa reflecting $52.5 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. In addition, in 2015 the Company earned $20.0 million in milestone payments from Sandoz upon receiving sole FDA approval for Glatopa and upon first commercial sale of Glatopa.
- The ANDA submitted by Sandoz for a three-times-a-week generic COPAXONE 40 mg (glatiramer acetate injection) is under FDA review and has received a target action date.
- 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.

Enoxaparin Sodium Injection

- Momenta earned $2.2 million and $5.1 million in product revenues on Sandoz's net sales of enoxaparin sodium injection in the fourth quarter of 2015 and for the year ended December 31, 2015, respectively.
- In November 2015, the Court of Appeals for the Federal Circuit (CAFC) vacated the District Court's summary judgment decision with respect to Amphastar, finding Amphastar's use of Momenta's U.S. Pat. 7,575,886 not to be protected under the "safe harbor" provisions in the Hatch-Waxman Act, and remanded the case back to the District Court. On February 17, 2016, the CAFC denied Amphastar's petition for rehearing.

Biosimilars:

- In the fourth quarter of 2015, Momenta and Baxalta announced the initiation of a pivotal clinical trial for M923, a biosimilar candidate of HUMIRA® (adalimumab). The companies also announced that M923 met the primary endpoints in a study to evaluate the pharmacokinetics of M923 compared to both US and EU sourced HUMIRA reference products. The companies are targeting first regulatory submission in 2017 and a first commercial launch in 2018.
- 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). Under the collaboration agreement, Mylan has agreed to pay Momenta an upfront cash payment of $45 million. In addition, each Company will share equally in the cost and profits with respect to products, with Mylan funding its share of expenses, in part, through up to $200 million in contingent milestone payments. On February 9, 2016, the companies received clearance for the collaboration under the Hart-Scott-Rodino Antitrust Improvements Act.
- 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)

- Following the institution of a protocol amendment in December 2015, the Company resumed patient enrollment in its ongoing Phase 2 trial of necuparanib in pancreatic cancer. In November 2015, Momenta had put a temporary hold on patient enrollment in its ongoing Phase 2 trial of necuparanib following receipt of recommendations from the Company's independent Data Safety Monitoring Board (DSMB) to develop guidelines for diagnosing and managing thrombocytopenia, based on a limited number of specific toxicities observed in the study. 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 publish and/or present updated results at a medical conference in 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 mid-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.

Fourth Quarter and Year End 2015 Financial Results

Total revenues for the fourth quarter of 2015 were $22.4 million (including Glatopa product revenue of $15.6 million), compared to $21.2 million for the same period in 2014. For the year ended December 31, 2015, total revenues were $89.7 million (including Glatopa product revenue of $43.4 million), compared to $52.3 million for 2014. Glatopa was launched in June 2015.

Enoxaparin product revenue decreased from $4.7 million for the fourth quarter of 2014 to $2.2 million for the same period in 2015. For the year ended December 31, 2015 , total enoxaparin product revenue was $5.1 million compared to $19.9 million for 2014. 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 fourth quarter of 2015 was $4.6 million compared to the $16.4 million recorded in the same quarter last year. The decrease is primarily due to the $12.0 million M923 technical development milestone earned under the Baxalta Agreement in the fourth quarter of 2014. For the year ended December 31, 2015, collaborative research and development revenues were $41.1 million, compared to $32.3 million for 2014. The increase is primarily due to $20.0 million in milestone payments earned upon sole FDA approval and first commercial sale of Glatopa in 2015.

Research and development expenses for the fourth quarter of 2015 were $37.6 million, compared to $26.2 million for the same period in 2014. The increase of $11.4 million, or 44%, from the 2014 period was due to increases of $9.3 million in third-party research and process development costs for our biosimilar and novel autoimmune drug programs, $1.6 million in personnel-related expenses and $0.5 million in necuparanib Phase 2 clinical trial expenses. For the year ended December 31, 2015, research and development expenses were $126.0 million compared to $106.5 million for the year ended 2014. The increase of $19.5 million in research and development expenses, or 18%, from 2014 to 2015 resulted from increases of

$17.6 million in third-party research and process development costs for our biosimilar and novel autoimmune drug programs, $3.3 million in necuparanib Phase 2 clinical trial expenses and $1.4 million in nonclinical studies for our novel autoimmune and early stage biosimilar programs. The increases were partly offset by decreases of $2.5 million for research supplies and $0.3 million in personnel-related expenses.

General and administrative expenses for the quarter ended December 31, 2015, were $14.4 million, compared with $11.1 million for the same period in 2014. The increase of $3.3 million, or 30%, was due to a $2.1 million increase in professional fees and a $1.2 million increase in personnel-related expenses. For the year ended December 31, 2015, general and administrative expenses were $48.1 million, compared to $45.2 million for the year ended 2014. The increase of $2.9 million, or 6%, resulted from increases of $2.3 million in professional fees, $0.8 million in facility related costs and $0.4 million in depreciation expense. The increases were partly offset by a $0.6 million decrease primarily in share-based compensation expenses associated with performance-based stock awards.

At December 31, 2015, Momenta had $350.0 million in cash, cash equivalents and marketable securities.

Financial Guidance

Today, Momenta provided guidance that it expects its operating expenses, excluding stock-based compensation and net of collaborative revenues, to be approximately $45 - $55 million per quarter for the first half of 2016.

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 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 46315104. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through February 25, 2016. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 46315104.

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 and product launches; timing of clinical trials and the availability and announcement of clinical data; and the timing of decisions related to patent litigation and other patent-related proceedings. Forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "could," "hope," "target," "project," "goal," "objective," "guidance," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek", "should," "will," "would," "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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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)

	December 31, 2015	December 31, 2014
Assets		
Cash and marketable securities	$ 350,044	$ 191,529
Accounts receivable	19,385	7,427
Restricted cash	20,660	20,719
Other assets	30,951	36,541
Total assets	$ 421,040	$ 256,216
Liabilities and Stockholders' Equity		
Current liabilities	$ 38,782	$ 23,789
Deferred revenue, net of current portion	12,213	25,508
Other long-term liabilities	69	551
Stockholders' equity	369,976	206,368
Total liabilities and stockholders' equity	$ 421,040	$ 256,216

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

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Collaboration revenues:				
Product revenue	$ 17,810	$ 4,747	$ 48,503	$ 19,963
Research and development revenue	4,583	16,432	41,147	32,287
Total collaboration revenue	22,393	21,179	89,650	52,250
Operating expenses:				
Research and development*	37,568	26,193	126,033	106,482
General and administrative*	14,373	11,125	48,051	45,164
Total operating expenses	51,941	37,318	174,084	151,646
Operating loss	(29,548)	(16,139)	(84,434)	(99,396)
Other income:				
Interest income	322	96	808	548
Other income	62	62	313	248
Total other income	384	158	1,121	796
Net loss	$ (29,164)	$ (15,981)	$ (83,313)	$ (98,600)
Basic and diluted net loss per share	$ (0.43)	$ (0.31)	$ (1.32)	$ (1.91)
Weighted average shares used in computing basic and diluted net loss per share	68,138	52,255	63,130	51,664
Comprehensive loss:				
Net loss	$ (29,164)	$ (15,981)	$ (83,313)	$ (98,600)
Net unrealized holding (losses) gains on available-for-sale marketable securities	(12)	(36)	20	(41)
Comprehensive loss	$ (29,176)	$ (16,017)	$ (83,293)	$ (98,641)

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

Research and development	$ 2,114	$ 1,449	$ 5,145	$ 6,204
General and administrative	$ 2,539	$ 1,630	$ 6,295	$ 7,390

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