November 4, 2015

Momenta Pharmaceuticals Reports Third Quarter 2015 Financial Results

CAMBRIDGE, Mass., Nov. 04, 2015 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the third quarter ended September 30, 2015.

For the third quarter of 2015, the Company reported total revenues of $13.8 million, including $8.7 million of Glatopa™ (glatiramer acetate injection) profit share. For the nine months ended September 30, 2015, the Company reported total revenues of $67.3 million, including $27.9 million in product revenues from Sandoz's sales of Glatopa. Momenta reported a net loss of $(30.1) million, or $(0.44) per share for the third quarter compared to a net loss of $(29.1) million, or $(0.56) per share for the same period in 2014. For the nine months ended September 30, 2015, the Company reported a net loss of $(54.1) million, or $(0.88) per share compared to a net loss of $(82.6) million, or $(1.61) per share for the same period in 2014. At September 30, 2015, the Company had cash, cash equivalents, and marketable securities of $374.9 million.

"The launch of Glatopa is going according to plan with Glatopa scripts currently representing approximately 25% to 30% of the once daily glatiramer acetate market," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "As the first marketed generic version of a multiple sclerosis drug, Glatopa is bringing value to both patients and payors."

"We continue to advance our biosimilar and novel drug programs. Our Phase 2 study of necuparanib in pancreatic cancer is advancing and M923, our biosimilar HUMIRA® candidate, has entered a pivotal clinical trial," continued Mr. Wheeler. "Our ongoing development activities should also allow us to move M834, our biosimilar ORENCIA® candidate, and our two novel recombinant autoimmune candidates into the clinic in 2016."

Third Quarter Highlights and Recent Events

Complex Generics:

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

- Sandoz launched Glatopa on June 18, 2015. In the third quarter of 2015, Momenta recorded $8.7 million in product revenues from Sandoz's Glatopa sales. Glatopa is experiencing positive trade uptake, although the impact on third quarter sales was limited as launch inventory continues to be worked through. In the second quarter of 2015 Momenta's share of profit on sales of Glatopa was $28.2 million, and after a deduction of $9.0 million in reimbursement to Sandoz of the Company's share of pre-launch Glatopa-related legal expenses, the Company recorded $19.2 million in product revenue.
- The ANDA for a three-times-a-week generic COPAXONE 40 mg (glatiramer acetate injection), submitted by Sandoz, is under FDA review.

Enoxaparin Sodium Injection

- The Company continues to pursue the patent infringement case related to Momenta's U.S. Pat. 7,575,886 against Amphastar and Actavis. In July 2015, the U.S. Solicitor General, at the request of the Court of Appeals for the Federal Circuit, filed a brief in the case that supported Momenta's interpretation of the scope of the "safe harbor" provisions under the Hatch Waxman Act. A CAFC decision is expected in 2015.

Biosimilars:

- In October 2015, Momenta and Baxalta announced the initiation of a pivotal clinical trial for M923, a biosimilar version of HUMIRA® (adalimumab). The trial is a randomized, double blind, active control, multi-center, global study in patients with chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. The companies are targeting first regulatory submission in 2017 and a first commercial launch in 2018.
- Momenta continues to develop M834, a biosimilar version of ORENCIA® (abatacept), and its portfolio of other biosimilar candidates and is in active discussions with potential partners to collaborate on the development and commercialization

of a portfolio of its biosimilar candidates.

Novel Drug:
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 available in the first half of 2017.
- The Company continues to collect data from the Phase 1 study and plans to publish and/or present updated results following completion of the study.

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 entering the clinic in late 2016, and is continuing its efforts to identify and explore potential partnering opportunities for the further development and commercialization of its hsIVIg program.

Third Quarter 2015 Financial Results

Total revenues for the third quarter of 2015 were $13.8 million compared to $9.3 million for the same period in 2014. Total revenues for the third quarter of 2015 includes $8.7 million in product revenue, which represents 50% of contractual profit earned from Sandoz's sale of Glatopa.

Enoxaparin product revenue decreased from $4.7 million for the third quarter of 2014 to zero for the same period in 2015. The decrease in enoxaparin product revenue was primarily due to the amendment of the enoxaparin sodium injection collaboration agreement in June 2015 which replaced Sandoz' obligation to pay the Company a royalty on net sales with an obligation to pay 50% of profit on sales. In the third quarter of 2015, Sandoz did not earn a profit on its sales of enoxaparin due to continued competitive pricing.

Collaborative research and development revenue for the third quarter of 2015 was $5.1 million, compared to the $4.6 million recorded in the same quarter last year. The increase is primarily due to an increase in the quarterly amortization of the upfront payment under the Baxalta collaboration.

Research and development expenses for the third quarter of 2015 were $31.7 million, compared to $27.5 million for the same period in 2014. The increase of $4.2 million, or 15%, from the 2014 period primarily resulted from increases of $2.0 million in nonclinical and manufacturing expenditures to advance the novel autoimmune programs, $1.8 million in clinical trial expenses as the necuparanib Phase 2 clinical trial continued to enroll patients and $0.3 million in share-based compensation expense associated with performance-based stock awards.

General and administrative expenses for the quarter ended September 30, 2015, were $12.5 million, compared with $11.1 million for the same period in 2014. The increase of $1.4 million, or 13%, from the 2014 period primarily resulted from increases of $0.8 million in share-based compensation associated with performance-based stock awards and $0.3 million in professional fees.

At September 30, 2015, Momenta had $374.9 million in cash, cash equivalents and marketable securities. This cash position excludes restricted cash of $20.7 million, of which $17.5 million is reserved as collateral for a security bond related to enoxaparin legal proceedings, and $3.2 million for letters of credit related to the company's two leased facilities.

Financial Guidance
Today, Momenta provided guidance that it expects its operating expenses, excluding stock-based compensation and net of collaborative revenues, to be approximately $40 - $42 million per quarter for the fourth quarter of 2015.

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 60061735. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through November 11, 2015. To access the replay, please dial (855) 859-2056

(domestic) or (404) 537-3406 (international) and provide the access code 60061735.

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 2015; future operating expenses; program development and partnering 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 June 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)

	September 30, 2015	December 31, 2014
Assets		
Cash and marketable securities	$ 374,869	$ 191,529
Accounts receivable	11,060	7,427
Restricted cash	20,660	20,719
Other assets	31,617	36,541
Total assets	$ 438,206	$ 256,216
Liabilities and Stockholders' Equity		
Current liabilities	$ 30,159	$ 23,789
Deferred revenue, net of current portion	14,656	25,508
Other long-term liabilities	129	551
Stockholders' equity	393,262	206,368
Total liabilities and stockholders' equity	$ 438,206	$ 256,216

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration revenues:				

Product revenue	$ 8,666	$ 4,714	$ 30,693	$ 15,216
Research and development revenue	5,129	4,622	36,565	15,855
Total collaboration revenue	13,795	9,336	67,258	31,071
Operating expenses:				
Research and development*	31,733	27,508	88,466	80,289
General and administrative*	12,459	11,103	33,678	34,039
Total operating expenses	44,192	38,611	122,144	114,328
Operating loss	(30,397)	(29,275)	(54,886)	(83,257)
Other income:				
Interest income	252	112	486	452
Other income	95	62	251	186
Total other income	347	174	737	638
Net loss	$ (30,050)	$ (29,101)	$ (54,149)	$ (82,619)
Basic and diluted net loss per share	$ (0.44)	$ (0.56)	$ (0.88)	$ (1.61)
Weighted average shares used in computing basic and diluted net loss per share	68,004	51,545	61,442	51,456
Comprehensive loss:				
Net loss	$ (30,050)	$ (29,101)	$ (54,149)	$ (82,619)
Net unrealized holding gains (losses) on available-for-sale marketable securities	(4)	(26)	32	(5)
Comprehensive loss	$ (30,054)	$ (29,127)	$ (54,117)	$ (82,624)

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

Research and development	$ 2,122	$ 1,509	$ 3,031	$ 4,755
General and administrative	$ 2,435	$ 1,890	$ 3,756	$ 5,760

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Source: Momenta Pharmaceuticals, Inc.