February 10, 2014

Momenta Pharmaceuticals Reports Fourth Quarter and Year End 2013 Financial Results

CAMBRIDGE, Mass., Feb. 10, 2014 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the fourth quarter and year ended December 31, 2013.

For the fourth quarter of 2013, the company reported a net loss of $(30.1) million, or $(0.59) per share, compared to a net loss of $(17.7) million, or $(0.35) per share for the same period in 2012. For the year ended December 31, 2013, the company reported a net loss of $(108.4) million, or $(2.13) per share, compared to a net loss of ($58.6) million, or $(1.16) per share, for the same period in 2012. At December 31, 2013, the company had cash, cash equivalents, and marketable securities of $245.7 million compared to $340.6 million at December 31, 2012.

"We successfully executed on our 2013 corporate objectives and in doing so we have paved the way for value creation across our three businesses," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "In 2014, we continue to work towards FDA approval and commercial launch of M356, a generic version of Copaxone®, and we look forward to making a new affordable option available to patients. For our biosimilars business, we are projecting to achieve multiple development milestones, and we are planning to advance M402 in the clinic."

Fourth Quarter Highlights and Recent Events

Complex Generics Business:
M356, generic version of Copaxone® (Glatiramer Acetate Injection)

- The ANDA for M356 is under active review by the U.S. FDA. The company and its collaboration partner, Sandoz, are preparing for the potential launch of this generic in 2014, pending U.S. FDA approval.
- In December 2013, the District Court modified the injunctions to exclude the 2015 invalidated Copaxone patent and the permanent injunction now expires on May 24, 2014.

Enoxaparin Sodium Injection

- In the fourth quarter of 2013, Momenta earned $4.9 million in product revenues from enoxaparin sodium injection based on Sandoz reported net sales of $51 million.
- Momenta continues to pursue the patent infringement case of *Momenta Pharmaceuticals vs. Amphastar Pharmaceuticals, Inc*., where the Federal Circuit ruled that Amphastar's use of Momenta's patented manufacturing method is protected by the Hatch Waxman "safe harbor." In January 2014, Momenta appealed the District Court's final judgment to the Federal Circuit.

Biosimilar and Potentially Interchangeable Biologics Business:

- Momenta expects to achieve milestones in the second half of 2014 under its global biosimilar collaboration with Baxter for products M923 and M834. The aggregate value of these potential milestones is $19 million. M923 and M834 are biosimilars for branded biologics indicated for certain autoimmune and inflammatory diseases. For M923, the company expects to achieve a technical development milestone. In addition, Momenta and Baxter are pursuing a global regulatory strategy for M923 and expect to enter the clinic in Europe in the second half of 2014, which also triggers a milestone payment. For M834, the company expects to achieve a pre-defined development milestone.
- Baxter's option to select up to three additional biosimilars to be included in the collaboration expires in February 2015.
- Momenta is continuing to develop M511, a monoclonal antibody for oncology, and may seek a new collaboration partner to assist in its development and commercialization.
- In December 2013, Michael Franken, M.D., joined Momenta as President, Biosimilars Business to oversee the operational management of the company's biosimilars programs, including the collaboration with Baxter, strategic planning, P&L responsibility, and other supporting activities.

Novel Drug Business:
M402 novel oncology candidate

- Momenta expects to have clinical data in the first half of 2014 from Part A of a Phase 1/2 proof-of-concept trial evaluating M402 in combination with Abraxane® (nab-paclitaxel) and gemcitabine in patients with advanced metastatic pancreatic cancer.
- The open label Phase 1/2 trial has completed several dose escalation cohorts, and based on encouraging signs of tolerability Momenta continues to add cohorts at a higher dose of M402.
- The company plans to initiate Part B of the study by the end of 2014. Part B will be a randomized, controlled study to evaluate the antitumor activity of M402 in combination with Abraxane plus gemcitabine, versus Abraxane plus gemcitabine alone.
- Last month, Momenta researchers presented a poster entitled: "M402 Increases Gemcitabine Uptake into Pancreatic Tumors as a Result of Stromal Matrix Remodeling" at the 2014 Gastrointestinal Cancers Symposium.

Sialylation Technology Research

- In 2014, Momenta will continue to advance its sialylation technology research program by seeking to identify an Fc-containing recombinant product candidate by the end of the year. The company is investigating opportunities to partner further development of a sialylated plasma-derived IVIG.

Other Research

- In December 2013, Momenta entered into an agreement with AnaptysBio to support its research programs. Under the agreement, AnaptysBio will attempt to generate several novel antibodies against a specific therapeutic target using its proprietary SHM-XEL™ platform. If AnaptysBio is successful, Momenta has an option to acquire a predefined number o the antibodies for development as drug candidates.
- Momenta continues to seek and evaluate research collaborations to provide capabilities to broaden and accelerate its novel drug programs.

Fourth Quarter and Year End 2013 Financial Results
Total revenues for the fourth quarter of 2013 were $12.8 million (including enoxaparin product revenue of $4.9 million), compared to $12.7 million (including enoxaparin product revenue of $10.8 million) for the same period in 2012. Sandoz reported fourth quarter 2013 enoxaparin net sales of $51 million versus $85 million for the fourth quarter 2012. The decrease in enoxaparin product revenue reflects lower prices, as well as decreased unit sales due to lower market share. For the year ended December 31, 2013, total revenue was $35.5 million, compared to $63.9 million for 2012, also due to lower enoxaparin prices and market share resulting from increased competition.

Collaborative research and development revenue for the fourth quarter of 2013 was $7.8 million, compared to $1.9 million in the same quarter last year. For the year ended December 31, 2013, collaborative research and development revenues were $18.8 million, compared to $9.1 million for the year ended 2012. The increases in both periods are due to an increase of reimbursable M923 expenses incurred in connection with the Baxter collaboration.

Research and development expenses for the fourth quarter of 2013 were $32.2 million, compared to $21.5 million for the same period in 2012. The increase of $10.7 million in research and development expenses from the fourth quarter of 2012 to the fourth quarter of 2013 resulted from an increase of $7.2 million in biosimilars process development and research costs, $1.5 million in personnel expenses and $1.6 million in facilities-related expenses. For the year ended December 31, 2013, research and development expenses were $104.0 million, compared to $80.3 million for the year ended 2012. The increase of $23.7 million in research and development expenses from 2012 to 2013 resulted from an increase of $14.7 million in biosimilar process development and research costs, $6.4 million in personnel and facilities-related expenses, and $1.3 million in professional fees.

General and administrative expenses for the quarter ended December 31, 2013, were $10.8 million, compared with $9.4 million for the same period in 2012. For the year ended December 31, 2013, general and administrative expenses were $41.1 million, compared to $43.7 million for the year ended 2012. The increase in the fourth quarter of 2013 and the decrease from 2012 to 2013 was primarily due to the timing of legal fees related to patent litigation.

At December 31, 2013, Momenta had $245.7 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 its 2014 total operating expenses, excluding stock-based compensation and net of collaborative revenues, are expected to average $30 to $32 million per quarter. For 2014, Momenta is projecting that its net cash usage, excluding revenue from the potential launch of M356, will average approximately $30 million per quarter, with quarterly cash burn in the second half of 2014 partially offset by an expected $19 million from milestone payments earned under the Baxter collaboration.

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 through March 10, 2014.

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 42665842. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through February 24, 2014. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 42665842.

About Momenta
Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture 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 products

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, the Company's revenue, expenses, including total operating expenses for 2014, comments regarding fourth quarter revenue as indicative of future enoxaparin revenue, potential approval and launch of M356, anticipated achievement of development milestones, including milestones under the Baxter collaboration in 2014, and cash usage, and other results of operations, our expected product development and collaboration milestones and timing for clinical and non-clinical results, our plans for future research and development investment, and our other product development plans and expectations constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "hope," "target," "project," "goals," "potential," "predict," "might," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors referred to in the company's Quarterly Report on Form 10-Q for quarter ended September 30, 2013 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Momenta 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. Momenta 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, 2013	December 31, 2012
Assets		
Cash and marketable securities	$ 245,682	$ 340,603
Accounts receivable	13,095	10,811
Restricted cash	20,719	19,971
Other assets	37,319	35,244
Total assets	$ 316,815	$ 406,629
Liabilities and Stockholders' Equity		
Current liabilities	$ 21,942	$ 18,161
Deferred revenue, net of current portion	24,024	27,269
Other long-term liabilities	1,012	712

Stockholders' equity	269,837	360,487
Total liabilities and stockholders' equity	$ 316,815	$ 406,629

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Statements of Comprehensive Loss

(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2013	**2012**	**2013**	**2012**
Collaboration revenues:				
Product revenue	$ 4,903	$ 10,812	$ 16,701	$ 54,772
Research and development revenues	7,847	1,916	18,764	9,149
Total collaboration revenue	12,750	12,728	35,465	63,921
Operating expenses:				
Research and development*	32,238	21,540	103,999	80,345
General and administrative*	10,848	9,373	41,057	43,682
Total operating expenses	43,086	30,913	145,056	124,027
Operating loss	(30,336)	(18,185)	(109,591)	(60,106)
Other income (expense):				
Interest income	214	288	950	1,238
Other income	60	220	233	220
Total other income	274	508	1,183	1,458
Net loss	$ (30,062)	$ (17,677)	$ (108,408)	$ (58,648)
Net loss per share:				
Basic	$ (0.59)	$ (0.35)	$ (2.13)	$ (1.16)
Diluted	$ (0.59)	$ (0.35)	$ (2.13)	$ (1.16)
Weighted average shares outstanding:				
Basic	51,185	50,547	50,907	50,411
Diluted	51,185	50,547	50,907	50,411
Comprehensive loss	$ (30,157)	$ (17,737)	$ (108,494)	$ (58,456)

*Includes the following share-based compensation expense:				
Research and development	$ 1,551	$ 1,515	$ 5,520	$ 5,832
General and administrative	$ 1,916	$ 1,937	$ 7,302	$ 7,880

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