February 17, 2015

# Momenta Pharmaceuticals Reports Fourth Quarter and Year End 2014 Financial Results

CAMBRIDGE, Mass., Feb. 17, 2015 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the fourth quarter and year ended December 31, 2014.

For the fourth quarter of 2014, the company reported a net loss of $(16.0) million, or $(0.31) per share, compared to a net loss of $(30.1) million, or $(0.59) per share for the same period in 2013. For the year ended December 31, 2014, the company reported a net loss of $(98.6) million, or $(1.91) per share, compared to a net loss of ($108.4) million, or $(2.13) per share, for the same period in 2013. At December 31, 2014, the company had cash, cash equivalents, and marketable securities of $191.5 million compared to $245.7 million at December 31, 2013.

"2014 was a very productive year for Momenta. We successfully executed on many of our corporate objectives including the achievement of multiple development milestones in our biosimilars collaboration with Baxter, initiation of a Phase 2 clinical study of necuparanib in pancreatic cancer, and the introduction of three promising autoimmune pipeline candidates further broadening our novel drug portfolio," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals.

"In our biosimilars business, Baxter has opted not to elect any additional biosimilars for development and has terminated their participation in the M834 program as part of their corporate restructuring and portfolio review process. Our collaboration with Baxter on M923, biosimilar HUMIRA, remains strong and we look forward to discussions in 2015 with potential new partners for M834, a biosimilar version of ORENCIA, and our additional biosimilar programs," Wheeler continued.

"We expect 2015 to be another year of forward momentum across the business and importantly, we remain optimistic that FDA approval of our once-daily generic Copaxone ANDA is near, and we are prepared for a commercial launch in 2015."

**Fourth Quarter Highlights and Recent Events**

**Complex Generics:**

***M356, generic version of Copaxone® (Glatiramer Acetate Injection)***

- The ANDA for M356 continues to be under active review by the U.S. FDA. The company and its collaboration partner, Sandoz, are prepared for the potential launch of this generic in 2015, pending U.S. FDA approval.
- On January 20, 2015, the United States Supreme Court vacated the 2013 decision of the Court of Appeals for the Federal Circuit which found several of the Copaxone (20 mg/mL injection) patents, including the one remaining patent which expires on September 1, 2015, invalid for being indefinite. The Supreme Court overturned the long standing practice whereby the CAFC reviewed a District Court's claim interpretation without deference to the District Court's subsidiary factual findings made in the course of claim interpretation, and has instructed the appeals court to reconsider the validity of the patent under a standard that gives deference to a District Court's subsidiary factual findings made in the course of claim construction, while retaining the "de novo" nature of the ultimate legal conclusion on claim construction. The appeals court is expected to rehear the case and issue a new decision within a year.
- In August 2014, Momenta announced that the U.S. FDA accepted for review the ANDA for a 40 mg/mL three-times-weekly generic Copaxone, submitted by Sandoz Inc., Momenta's development and commercialization collaborator for this product candidate.

***Enoxaparin Sodium Injection***

- In the fourth quarter of 2014, Momenta earned $4.7 million in product revenues from enoxaparin sodium injection based on Sandoz reported net sales of $47 million.
- The Company continues to pursue the patent infringement case related to Momenta's U.S. Pat. 7,575,886 against Amphastar and Teva. In a 2012 decision, the Court of Appeals for the Federal Circuit (CAFC) held that Amphastar's use of Momenta's patented method is protected by the Hatch Waxman "safe harbor" (*Momenta Pharmaceuticals vs. Amphastar Pharmaceuticals, Inc*. Fed. Cir. Aug. 3, 2012). The safe harbor issue is on appeal at the CAFC again after a summary judgment decision subsequent to the 2012 CAFC decision. A hearing is expected during the first half of 2015 and a decision could be expected in 2015.

**Biosimilar and Potentially Interchangeable Biologics:**

- Due to Baxter's company restructuring and change to a strong focus on later stage biosimilar assets, on February 16, 2015, Baxter terminated its license to M834 under the collaboration agreement. Baxter also let expire its right to select additional targets for biosimilar development under the collaboration. Momenta and Baxter are continuing to collaborate on M923.
- In December 2014, Momenta announced the acceptance of a Clinical Trial Application (CTA) to initiate a clinical trial for M923, a biosimilar version of HUMIRA® (adalimumab), in Europe, in collaboration with Baxter International's biopharmaceutical business. Acceptance of the CTA triggered two milestone payments under the Baxter collaboration with an aggregate payment of $12 million. A pharmacokinetic clinical trial has been initiated in Europe.
- Momenta's second biosimilar candidate, M834, a biosimilar version of ORENCIA® (abatacept) and indicated for certain autoimmune and inflammatory diseases, achieved a pre-defined development milestone triggering a $7 million milestone payment from Baxter in the fourth quarter of 2014.
- Momenta will continue to develop M834 and will seek a new collaboration partner to assist in development and commercialization.
- Momenta continues to develop its portfolio of early stage biosimilar candidates and is in active discussions with potential collaboration partner(s) to assist in development and commercialization of its additional candidates.

**Novel Drugs:**
***Necuparanib (novel oncology candidate)***

- In October 2014, Momenta announced promising top-line results from the Part A of the Phase 1/2 study evaluating necuparanib in combination with Abraxane® (paclitaxel) and gemcitabine in patients with metastatic pancreatic cancer. The Company plans to present more mature data in mid-2015.
- Momenta also initiated the Phase 2 component of the necuparanib trial, which is a randomized, controlled study to evaluate the antitumor activity of necuparanib in combination with Abraxane plus gemcitabine, versus Abraxane plus gemcitabine alone. The Company expects to have clinical data available in the first half of 2017.
- In December 2014, the U.S. FDA granted Fast Track designation to the investigation of necuparanib as a first-line treatment in combination with Abraxane® and gemcitabine in patients with metastatic pancreatic cancer.

***Novel Autoimmune Drugs***
In October 2014, Momenta introduced three novel autoimmune candidates that are currently in various stages of preclinical development. These candidates include a hyper-sialylated IVIg (hsIVIg), a high potency alternative to IVIg, and two recombinant molecules: a Selective Immunomodulator of Fc receptors (SIF3) and an anti-FcRn monoclonal antibody. The recombinant molecules have been designed by leveraging the Company's knowledge of the anti-inflammatory effects of IVIg to maximize therapeutic benefit and patient convenience. Momenta believes these programs could have potential in a range of diseases that currently have few treatment options such as autoimmune neuropathies, autoimmune blood disorders and blistering skin diseases. The Company expects to continue to advance the recombinant candidates with a goal of entering the clinic in late 2016 and remains in active partnering discussions for its hsIVIg product.

**Fourth Quarter and Year End 2014 Financial Results**
Total revenues for the fourth quarter of 2014 were $21.2 million (including enoxaparin product revenue of $4.7 million), compared to $12.8 million (including enoxaparin product revenue of $4.9 million) for the same period in 2013. Sandoz reported fourth quarter 2014 enoxaparin net sales of $47 million versus $51 million for the fourth quarter 2013. The decrease in enoxaparin product revenue reflects lower prices. For the year ended December 31, 2014, total revenue was $52.3 million, compared to $35.5 million for 2013.

Collaborative research and development revenue for the fourth quarter of 2014 was $16.4 million, compared to $7.8 million in the same quarter last year. For the year ended December 31, 2014, collaborative research and development revenues were $32.3 million, compared to $18.8 million for the year ended 2013. The increases in both periods are primarily due to the $12.0 million in M923 technical development milestones earned under the Baxter Agreement and recognized as revenue in the fourth quarter of 2014. The $7.0 million milestone payment from Baxter for M834 was received in the fourth quarter of 2014 and will be recognized as revenue over the product's development period.

Research and development expenses for the fourth quarter of 2014 were $26.2 million, compared to $32.2 million for the same period in 2013. The decrease of $6.0 million in research and development expenses from the fourth quarter of 2013 to the fourth quarter of 2014 was primarily due to lower biosimilars process development and research costs. For the year ended December 31, 2014, research and development expenses were $106.5 million, compared to $104.0 million for the year ended 2013. The increase of $2.5 million in research and development expenses from 2013 to 2014 resulted from increases of: $4.8 million in personnel and facilities-related expenses; $2.5 million to advance the novel drug research program; $1.9 million in necuparanib clinical costs; and $1.0 million in laboratory supplies. These increases were offset by a decrease of $7.6 million primarily related to lower third-party process development, contract research costs and consulting fees incurred for our

biosimilars program.

General and administrative expenses for the quarter ended December 31, 2014, were $11.1 million, compared with $10.8 million for the same period in 2013. For the year ended December 31, 2014, general and administrative expenses were $45.2 million, compared to $41.1 million for the year ended 2013. The increase of $4.1 million from 2013 to 2014 was primarily due to increases of: $2.5 million in personnel and facilities-related costs; $0.6 million in allocated lab supplies; $0.4 million in professional fees; and $0.3 million in allocated depreciation expense.

At December 31, 2014, Momenta had $191.5 million in cash, cash equivalents and marketable securities. This cash position includes $18.3 million in net proceeds from the sale of approximately 1.7 million shares of common stock through the Company's "At the Market" (ATM) agreement with Stifel, Nicolaus & Company in the fourth quarter of 2014. 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 net cash usage, excluding revenue from the potential launch of M356, and excluding revenue from any potential new biosimilar collaboration(s), will be approximately $30 million for the first quarter of 2015, and thereafter, the Company is seeking to reduce its cash burn through new collaborative agreements for its biosimilar and/or new drug programs.

**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 70886529. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through February 20, 2015. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 70886529.

**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 future net cash usage, revenues and operating expense, timing for the generic Copaxone ANDA approval, timing and outcome of the patent litigation relating to generic Copaxone and the Company's enoxaparin patents, future biosimilar program development plans, timing of presenting additional necuparanib trial data and the timing of clinical trials for the Company's novel drug product candidates. 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," "target," "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, 2014, 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, 2014 | December 31, 2013 |
|---|---|---|
| **Assets** | | |
| Cash and marketable securities | $ 191,529 | $ 245,682 |
| Accounts receivable | 7,427 | 13,095 |
| Restricted cash | 20,719 | 20,719 |
| Other assets | 36,541 | 37,319 |
| Total assets | $ 256,216 | $ 316,815 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | $ 23,789 | $ 21,942 |
| Deferred revenue, net of current portion | 25,508 | 24,024 |
| Other long-term liabilities | 551 | 1,012 |
| Stockholders' equity | 206,368 | 269,837 |
| Total liabilities and stockholders' equity | $ 256,216 | $ 316,815 |

**MOMENTA PHARMACEUTICALS, INC.**

**Unaudited Condensed Statements of Comprehensive Loss**

(in thousands, except per share amounts)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| Collaboration revenues: | | | | |
| Product revenue | $ 4,747 | $ 4,903 | $ 19,963 | $ 16,701 |
| Research and development revenues | 16,432 | 7,847 | 32,287 | 18,764 |
| Total collaboration revenue | 21,179 | 12,750 | 52,250 | 35,465 |
| Operating expenses: | | | | |
| Research and development* | 26,193 | 32,238 | 106,482 | 103,999 |
| General and administrative* | 11,125 | 10,848 | 45,164 | 41,057 |
| Total operating expenses | 37,318 | 43,086 | 151,646 | 145,056 |
| Operating loss | (16,139) | (30,336) | (99,396) | (109,591) |
| Other income: | | | | |
| Interest income | 96 | 214 | 548 | 950 |
| Other income | 62 | 60 | 248 | 233 |
| Total other income | 158 | 274 | 796 | 1,183 |
| Net loss | $ (15,981) | $ (30,062) | $ (98,600) | $ (108,408) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.31) | $ (0.59) | $ (1.91) | $ (2.13) |
| Weighted average shares outstanding: | | | | |

| | | | | |
|---|---|---|---|---|
| Basic and diluted | 52,255 | 51,185 | 51,664 | 50,907 |
| Comprehensive loss | $ (16,017) | $ (30,157) | $ (98,641) | $ (108,494) |
| *Includes the following share-based compensation expense: | | | | |
| Research and development | $ 1,449 | $ 1,551 | $ 6,204 | $ 5,520 |
| General and administrative | $ 1,630 | $ 1,916 | $ 7,390 | $ 7,302 |

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