August 1, 2013

# Momenta Pharmaceuticals Reports Second Quarter 2013 Financial Results

CAMBRIDGE, Mass., Aug. 1, 2013 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today reported its financial results for the quarter ended June 30, 2013.

For the second quarter of 2013, the company reported a net loss of $28.8 million, or ($0.57) per share, compared with a net loss of $10.2 million, or ($0.20) per share, for the same period in 2012. At June 30, 2013, the company had cash, cash equivalents, and marketable securities of $300.2 million, compared with $340.6 million at December 31, 2012.

"We are extremely pleased with the recent opinion by the Federal Circuit that found several Copaxone® patents Teva asserted against Momenta and Sandoz invalid," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "The Court's decision clears the path to potentially launch M356, generic Copaxone, in the U.S. after the remaining patents expire in May 2014, pending FDA approval.

"In addition to the favorable Federal Circuit ruling, our 2013 achievements include advancing our lead biosimilar product M923 toward a planned IND submission in 2014 and executing on objectives for our biosimilars and novel drug programs," continued Mr. Wheeler.

**Second Quarter Highlights and Recent Progress**

**Complex Generics:**

***M356, generic version of Copaxone® (glatiramer acetate injection)***

- On July 26, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a written opinion in the patent litigation brought by Teva Pharmaceuticals against Momenta and Sandoz for infringement of nine U.S. patents associated with the submission to the FDA of an Abbreviated New Drug Application (ANDA) for generic Copaxone. The CAFC opinion followed oral arguments conducted in May. The CAFC narrowed the 2012 decision by the District Court for the Southern District of New York and invalidated several asserted patents, including the one non-Orange Book patent set to expire in September 2015.

  The CAFC ruling does not vacate the permanent injunctions. The case was remanded back to the District Court in order to modify the permanent injunction to exclude the invalidated patents consistent with the CAFC ruling.
- In July, the District Court for the Southern District of New York granted Momenta's and Sandoz' motion to dismiss another case asserted by Teva against the company alleging infringement of patents referred to as the "Gad patents" that involve molecular weight markers for Copaxone.
- The ANDA for M356 continues to be under review by the U.S. FDA.

***Enoxaparin Sodium Injection***

- In the second quarter of 2013, Momenta earned $1.6 million in Enoxaparin Sodium Injection product revenues based on Sandoz-reported net sales of $57 million. The product revenues for Momenta include royalties on the quarter's net sales, less a $3.8 million annual adjustment to Momenta's share of pre-commercial development expenses under its collaboration with Sandoz.
- In June, the Supreme Court of the United States denied to hear the case of *Momenta Pharmaceuticals vs. Amphastar Pharmaceuticals, Inc.* in which the U.S. Court of Appeals for the Federal Circuit held that Amphastar's use of Momenta's patented method was protected by the "safe harbor" provision from patent infringement under 35 U.S.C. sec. 271(e)(1).
- In July, the District Court of Massachusetts granted Amphastar and Teva's motions for summary judgment in the Enoxaparin patent suits as a result of the decision by the Court of Appeals. Momenta is considering options for appeal.

**Biosimilars and Potentially Interchangeable Biologics:**

- Momenta continues to advance toward achievement of defined milestones in 2014 for its three biosimilar products under

development with Baxter: M923 and M834 — two products targeting autoimmune and inflammatory indications, and M511 — a monoclonal antibody for oncology. The milestones are achievement of technical development criteria and the first submission of an Investigational New Drug (IND) application in 2014 for its lead biosimilar M923 as well as achievement of development criteria that would generate a license payment and a milestone payment for M511 and M834, respectively, in 2014.
- Momenta with its collaborator Baxter continues to evaluate additional products for development.

**Novel Products:**

***M402 Phase 1/2 proof-of-concept study***

- In April, Momenta amended its Phase 1/2 proof-of-concept study to evaluate M402 in combination with Abraxane® (nab-paclitaxel) and gemcitabine in patients with pancreatic cancer. The primary objectives of Part A are to evaluate safety and tolerability of M402 in combination with Abraxane and gemcitabine and to establish the dose of M402 to take forward into Part B. 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. Dosing of several cohorts in Part A has been completed, including one with the new regimen of M402 plus Abraxane and gemcitabine. Momenta expects to have data from Part A during the first half of 2014.

***Sialylation research program***

- In June, Rockefeller University was issued the first U.S. patent related to sialylation technology. Momenta is the exclusive licensee of the patent. The patent claims methods of inhibiting inflammation using intravenous immunoglobulin (IVIG)-derived, sialylated Fc regions and expires in 2028.
- Momenta continues to generate data to investigate and validate the biology of sialylated IVIG to inform the company's selection of the indication to potentially take forward into development, as well as to define the specific product, or products, to potentially advance to the clinic.

**Second Quarter 2013 Financial Results**

Total revenue for the second quarter of 2013 was $4.4 million (including product revenue of $1.6 million), compared with $21.9 million (including product revenue of $19.4 million) for the same period in 2012. Sandoz reported second quarter enoxaparin net sales of $57 million. The decrease in product revenue from the prior year was due to decreased unit sales due to lower market share and lower prices in response to competitor pricing reductions on Enoxaparin Sodium Injection. In the second quarter of 2013 and 2012, Momenta's product revenue was reduced by $3.8 million and $3.9 million, respectively, for an annual adjustment to contractual share of certain development and other expenses for Enoxaparin Sodium Injection. Momenta second quarter 2013 revenues also include $2.7 million in research and development revenue, including $0.7 million in amortization of the $33 million payment received from the Baxter collaboration.

Research and development expenses, including stock-based compensation, for the second quarter of 2013 were $22.0 million, compared with $20.0 million, including stock-based compensation, for the same period in 2012. The increase was primarily due to personnel and related costs associated with increased headcount to support development of the company's pipeline as well as process development, manufacturing, and research costs related to the company's biosimilars program.

General and administrative expenses for the second quarter of 2013 were $11.5 million, including stock-based compensation, compared with $12.4 million, including stock-based compensation, for the same period in 2012. The decrease of $0.9 million from same period in 2012 was primarily due to a decrease in professional fees principally due to decreased legal fees relating to Enoxaparin Sodium Injection patent litigation.

At June 30, 2013, Momenta had $300.2 million in cash, cash equivalents and marketable securities. This cash position excludes restricted cash of $17.5 million, which serves as collateral for a security bond related to enoxaparin legal proceedings, and $2.5 million related to a facility lease letter of credit.

**Financial Guidance**

Momenta confirmed its guidance for 2013 for total operating expenses, excluding stock compensation and net of collaborative revenues, averaging approximately $30 million per quarter. For 2013, Momenta is projecting that its net cash usage will average approximately $20 to $24 million per quarter for a total operating cash usage of approximately $80 to $90 million for 2013.

**Conference Call Information**

Management will host a conference call today, August 1, 2013 at 10:00 am EDT to discuss these results and provide an update

on the company. To access the call, please dial (877) 224-9084 (domestic) or (720) 545-0022 (international) prior to the scheduled conference call time and provide the access code 19648443. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through August 8, 2013. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 19648443.

A live audio webcast of the call will be available on the "Investors" section of the company's web site, 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 web site approximately two hours after the call and will be available through August 15, 2013.

**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 and other results of operations, including the quarter ended June 30, 2013, expectations regarding the review of the M356 ANDA by the FDA, expected achievement of product development milestones, the timing of legal developments and decisions, plans for future research and development investment, and other product development and research plans and expectations may 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 March 31, 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)

| | June 30, 2013 | December 31, 2012 |
|---|---|---|
| **Assets** | | |
| Cash and marketable securities | $ 300,160 | $ 340,603 |
| Accounts receivable | 3,099 | 10,811 |
| Restricted cash | 19,971 | 19,971 |
| Other assets | 34,529 | 35,244 |
| Total assets | $ 357,759 | $ 406,629 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | $ 16,829 | $ 18,161 |
| Deferred revenue, net of current portion | 25,412 | 27,269 |
| Other liabilities | 602 | 712 |
| Stockholders' equity | 314,916 | 360,487 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 357,759 | $ 406,629 |

**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(in thousands, except per share amounts)

(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2013** | **2012** | **2013** | **2012** |
| Collaboration revenues: | | | | |
| Product revenue | $ 1,628 | $ 19,352 | $ 7,024 | $ 41,382 |
| Research and development revenue | 2,733 | 2,511 | 4,940 | 4,709 |
| Total collaboration revenue | 4,361 | 21,863 | 11,964 | 46,091 |
| Operating expenses: | | | | |
| Research and development* | 21,994 | 20,011 | 44,326 | 38,572 |
| General and administrative* | 11,516 | 12,353 | 21,233 | 23,310 |
| Total operating expenses | 33,510 | 32,364 | 65,559 | 61,882 |
| Operating loss | (29,149) | (10,501) | (53,595) | (15,791) |
| Other income: | | | | |
| Interest income | 243 | 335 | 512 | 642 |
| Other income | 58 | — | 118 | — |
| Total other income | 301 | 335 | 630 | 642 |
| Net loss | $ (28,848) | $ (10,166) | $ (52,965) | $ (15,149) |
| Basic and diluted net loss per share | $ (0.57) | $ (0.20) | $ (1.04) | $ (0.30) |
| Weighted average shares used in computing basic and diluted net loss per share | 50,746 | 50,354 | 50,690 | 50,297 |
| Comprehensive loss | $ (28,872) | $ (10,206) | $ (53,054) | $ (15,082) |

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

| | | | | |
|---|---|---|---|---|
| Research and development | $ 1,487 | $ 1,432 | $ 2,610 | $ 2,786 |
| General and administrative | $ 1,842 | $ 2,025 | $ 3,591 | $ 3,925 |

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Source: Momenta Pharmaceuticals