November 5, 2014

Momenta Pharmaceuticals Reports Third Quarter 2014 Financial Results

CAMBRIDGE, Mass., Nov. 5, 2014 (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 third quarter ended September 30, 2014.

For the third quarter of 2014, the company reported a net loss of $29.1 million, or $(0.56) per share, compared to a net loss of $25.4 million, or $(0.50) per share for the same period in 2013. At September 30, 2014, the company had cash, cash equivalents, and marketable securities of $176.5 million.

"In the third quarter we continued to make important progress across our complex generics, biosimilars and novel drug programs," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We discussed this progress at our R&D day in early October where we announced encouraging top-line results from the Part A phase of our necuparanib trial and unveiled three promising novel autoimmune drug candidates that we expect to reach clinical stage in 2016. We also discussed the progress we made in our biosimilars portfolio and in building on that progress, we are pleased to report that a European clinical trial application has been filed for M923, our biosimilar version of Humira® (adalimumab) in collaboration with Baxter. In addition, we recently achieved an important milestone in the development of our second biosimilar candidate, M834, also in development with Baxter.

"In a short amount of time our innovative technology platform has allowed us to develop a robust portfolio of product candidates that we believe have the potential to create significant value for our shareholders in the coming years and beyond," continued Mr. Wheeler.

Third 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 preparing for the potential launch of this generic, pending U.S. FDA approval.
- On October 15, 2014, the Supreme Court of the United States heard oral arguments on the *Teva Pharmaceuticals USA v. Sandoz* case. The Supreme Court is not expected to rule until a later date.
- On August 28, 2014, Momenta announced that the U.S. FDA accepted for review the ANDA for a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL), submitted by Sandoz Inc., Momenta's development and commercialization collaborator for this product candidate. Momenta believes that based on publicly-available information, should the ANDA be approved, it would be eligible for 180-day first-to-file exclusivity under Hatch-Waxman.

Enoxaparin Sodium Injection

- In the third quarter of 2014, Momenta earned $4.7 million in product revenues from enoxaparin sodium injection based on Sandoz reported net sales of $48 million.

Biosimilar and Potentially Interchangeable Biologics:

- Momenta and Baxter are pursuing a global regulatory strategy for M923 (a biosimilar version of Humira®) and have submitted a European clinical trial application, which, upon approval, will allow for clinical initiation shortly thereafter. Acceptance of the clinical trial application triggers two milestones under the Baxter collaboration with an aggregate payment of $12 million.
- Momenta also announced that its development of M834, the Company's second biosimilar indicated for certain autoimmune and inflammatory diseases being developed in collaboration with Baxter, achieved a pre-defined $7 million development milestone in October 2014.

Novel Drugs:

Necuparanib (novel oncology candidate)

- On October 9, 2014 Momenta announced promising top-line results from the Part A dose escalation component of the Phase 1/2 trial evaluating necuparanib in combination with Abraxane® (nab-paclitaxel) and gemcitabine in patients with advanced metastatic pancreatic cancer. Necuparanib showed favorable tolerability and encouraging early signals of potential efficacy.
- In October 2014, the Company initiated patient screening for the Part B component of the Phase 1/2 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.

Novel Autoimmune Drugs
The Company announced it is advancing three novel autoimmune candidates toward clinical development over the next 18 to 24 months including:

- Hyper-sialylated IVIg, or hsIVIg, a high potency alternative to IVIg that in a number of in-vivo models yields a uniform high-activity, anti-inflammatory therapeutic effect at a much lower dose and may enable simpler administration and superior efficacy in certain autoimmune disease indications;
- Selective immunomodulator of Fc receptors, or SIF3, a novel recombinant protein designed to have enhanced avidity and affinity for Fc receptors, potentially making it a potent blocker of this system and treatment for autoimmune disorders where this biological pathway is activated. Momenta plans to advance this program with the goal of developing an IVIg-like efficacy profile at lower doses, potentially reducing the risks associated with plasma-derived products; and
- Anti-FcRn antibody, a fully-human monoclonal antibody that blocks the neonatal Fc receptor (FcRn). FcRn recycles IgG antibodies, enabling a long half-life. Preclinical data demonstrates that blocking the FcRn receptor with Momenta's anti-FcRn antibody effectively inhibits the binding of IgGs and leads to their rapid clearance. Momenta believes these data demonstrate high potential for acute and chronic/intermittent therapies in a broad range of autoantibody driven disease indications.

Third Quarter 2014 Financial Results
Total revenues for the third quarter of 2014 were $9.3 million (including enoxaparin product revenue of $4.7 million), compared to $10.8 million (including enoxaparin product revenue of $4.8 million) for the same period in 2013. Sandoz reported third quarter 2014 enoxaparin net sales of $48 million, compared to $58 million for the third quarter of 2013.

Collaborative research and development revenue for the third quarter of 2014 was $4.6 million, compared to $6.0 million in the same quarter last year. The decrease of $1.4 million in collaborative revenue between comparable periods is due to lower reimbursable M923 research and development services and expenses incurred in connection with the Baxter Agreement.

Research and development expenses for the third quarter of 2014 were $27.5 million, compared to $27.4 million for the same period in 2013. The increase of $0.1 million from the 2013 period to the 2014 period resulted from increases of: $2.0 million in costs incurred to advance our research program; $1.2 million in necuparanib clinical costs incurred to complete the Part A dose escalation component of the Phase 1/2 trial; and $0.9 million in facility related costs due to additional subleased laboratory and office space. These increases were offset by a $4.0 million decrease in consulting, third-party process development and contract research costs related to the Company's biosimilars program.

General and administrative expenses for the third quarter ended September 30, 2014 were $11.1 million, compared with $9.0 million for the same period in 2013. The increase of $2.1 million in the third quarter of 2014 was due to: $0.9 million in professional fees, driven mainly by corporate and IP legal fees; $0.7 million in rent and facility-related costs due to additional subleased laboratory and office space; and $0.5 million in salary, salary-related and stock compensation.

At September 30, 2014, Momenta had $176.5 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.

Financial Guidance
Today, Momenta confirmed its financial guidance for the second half of 2014: Momenta previously projected that total 2014 operating expenses, excluding stock-based compensation and net of collaborative revenues, would be $28 to $30 million per quarter and, in the first three quarters of 2014, the average amount per quarter was $30 million. For the fourth quarter of 2014, the Company projects total operating expenses, excluding stock-based compensation and net of collaborative revenues, to be $30 to $32 million. Momenta previously projected that its net cash usage in 2014, excluding revenue from the potential launch of M356 and milestones earned from the Baxter biosimilars collaboration, would average approximately $26 million per quarter. Through the first three quarters of 2014, net cash usage has averaged $23 million per quarter. Cash burn for the fourth quarter of 2014 is expected to be in line with our previous guidance and is projected to be partially offset by $19 million from milestone payments earned under the Baxter collaboration, although a portion of these milestone payments could be received in the first 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 through November 12, 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 23751819. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through August 14, 2014. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 23751819.

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.

Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

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 anticipated initiation of a European clinical trial, expected receipt or timing of milestone payments in its development programs with Baxter, future achievements and related value-creation in the Company's antibody research and development programs and product opportunities. 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 the quarter ended June 30, 2014 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)

	September 30, 2014	December 31, 2013
Assets		
Cash and marketable securities	$ 176,457	$ 245,682
Accounts receivable	7,649	13,095
Restricted cash	20,719	20,719
Other assets	36,710	37,319
Total assets	$ 241,535	$ 316,815
Liabilities and Stockholders' Equity		
Current liabilities	$ 18,615	$ 21,942
Deferred revenue, net of current portion	21,863	24,024
Other long-term liabilities	701	1,012
Stockholders' equity	200,356	269,837

Total liabilities and stockholders' equity	$ 241,535	$ 316,815

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,	
	2014	**2013**	**2014**	**2013**
Collaboration revenues:				
Product revenue	$ 4,714	$ 4,774	$ 15,216	$ 11,798
Research and development revenue	4,622	5,977	15,855	10,918
Total collaboration revenue	9,336	10,751	31,071	22,716
Operating expenses:				
Research and development*	27,508	27,435	80,289	71,771
General and administrative*	11,103	8,977	34,039	30,202
Total operating expenses	38,611	36,412	114,328	101,973
Operating loss	(29,275)	(25,661)	(83,257)	(79,257)
Other income:				
Interest income	112	224	452	736
Other income	62	55	186	174
Total other income	174	279	638	910
Net loss	$ (29,101)	$ (25,382)	$ (82,619)	$ (78,347)
Basic and diluted net loss per share	$ (0.56)	$ (0.50)	$ (1.61)	$ (1.54)
Weighted average shares used in computing basic and diluted net loss per share	51,545	51,055	51,456	50,813
Comprehensive loss:				
Net loss	$ (29,101)	$ (25,382)	$ (82,619)	$ (78,347)
Net unrealized holding gains (losses) on available-for-sale marketable securities	(26)	98	(5)	9
Comprehensive loss	$ (29,127)	$ (25,284)	$ (82,624)	$ (78,338)

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

Research and development	$ 1,509	$ 1,359	$ 4,755	$ 3,969
General and administrative	$ 1,890	$ 1,796	$ 5,760	$ 5,387

CONTACT: INVESTOR CONTACT:

Sarah Carmody

Momenta Pharmaceuticals

1-617-395-5189

IR@momentapharma.com

MEDIA CONTACT:

Karen Sharma

MacDougall Biomedical Communications

1-781-235-3060

Momenta@macbiocom.com

Source: Momenta Pharmaceuticals

News Provided by Acquire Media