

MOMENTA PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 05/03/12 for the Period Ending 05/03/12

Address	675 WEST KENDALL STREET CAMBRIDGE, MA 02142
Telephone	617 491-9700
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Industry	Biotechnology & Drugs
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported) **May 3, 2012**

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50797
(Commission File Number)

04-3561634
(IRS Employer
Identification No.)

675 West Kendall Street, Cambridge, MA
(Address of Principal Executive Offices)

02142
(Zip Code)

(617) 491-9700
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition

On May 3, 2012, Momenta Pharmaceuticals, Inc., a Delaware corporation, announced its financial results for the quarter ended March 31, 2012. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1. Press Release issued by Momenta Pharmaceuticals, Inc. on May 3, 2012.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer
(Principal Financial Officer)

Date: May 3, 2012

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Momenta Pharmaceuticals, Inc. on May 3, 2012.

MOMENTA PHARMACEUTICALS, INC.

675 WEST KENDALL STREET

T: 617.491.9700 F: 617.621.0430

CAMBRIDGE, MA 02142

WWW.MOMENTAPHARMA.COM



**Momenta Pharmaceuticals Reports
First Quarter 2012 Financial Results**

- Phase 1/2 proof-of-concept trial for novel oncology drug candidate, M402, initiated; patient screening underway at trial sites in the U.S.

CAMBRIDGE, MA — May 3, 2012 — 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 March 31, 2012.

For the first quarter of 2012, the company reported a net loss of \$5.0 million, or (\$0.10) per share, compared to a net income of \$57.0 million, or \$1.13 per diluted share, for the same period in 2011. At March 31, 2012, the company had cash, cash equivalents, and marketable securities of \$382.3 million, compared to \$348.4 million at December 31, 2011.

“Thanks to the success of enoxaparin we have a strong balance sheet to support our business as we invest in our generic Copaxone® program, our new follow-on biologics collaboration with Baxter, and our emerging novel drug portfolio,” said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. “Although competition for generic enoxaparin has reduced the revenue we receive for the product, it continues to be an important source of cash flow for the company. Our innovative technology platform that we developed over the last decade provides a strong foundation for future advances that we believe will drive value for the company, cost savings for the healthcare system and significant benefit for our shareholders.”

First Quarter Highlights and Recent Progress

Complex Generics Program:

Enoxaparin sodium injection program update

- Last week, Momenta’s collaborator, Sandoz, launched enoxaparin sodium injection, USP 3mL vials. Launch of this vial formulation completes Sandoz’s full generic Lovenox® product line.
- In January, an at-risk launch of a competitor’s generic Lovenox triggered a change in the revenue Momenta receives from its collaborator, Sandoz, from a hybrid profit share/royalty to a tiered royalty.

Follow-on Biologics Program:

Baxter collaboration effective

- In February, Momenta’s follow-on biologics collaboration with Baxter became effective following expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.
- In the first quarter, Momenta received a \$33 million upfront cash payment under the Baxter agreement. The company will recognize the upfront payment as collaborative research and development revenue over the term of the development period.
- Momenta continues to invest in building out its biologic infrastructure to ensure the company has the resources required to advance up to six biosimilars to be developed under the Baxter agreement.

Novel Drug Program:

Productivity in research and development programs

- Momenta today announced that patient screening is underway in Part A of a two-part Phase 1/2 proof-of-concept trial for M402 in people with advanced metastatic pancreatic cancer. The primary objectives of Part A are to evaluate safety and tolerability of M402 in combination with gemcitabine and to establish the dose of M402 to take forward into Part B,

which is a larger, randomized controlled study to evaluate the antitumor activity of M402 in combination with gemcitabine versus gemcitabine alone in patients with metastatic pancreatic cancer. Data from Part A are expected in the first half of 2013. M402 is a novel oncology drug candidate that has been shown in non-clinical studies to affect tumor progression and metastasis through disruption of multiple pathways.

- In the first quarter, Momenta began a research effort to apply recently acquired sialic switch technology for the development of a sialylated intravenous immunoglobulin (IVIG) drug candidate.

First Quarter 2012 Financial Results

Total revenue for the first quarter of 2012 was \$24.2 million (including product revenue of \$22.0 million), compared to \$78.2 million (including product revenue of \$75.8 million) for the same period in 2011. The decrease in revenue was principally driven by a decrease in enoxaparin product revenues following the September 2011 approval and January 2012 launch of a competitor's generic Lovenox. As a result, in January 2012, the company's product revenues earned on net sales of enoxaparin by Sandoz transitioned to a tiered royalty from a hybrid profit share/royalty agreement. Sandoz reported first quarter enoxaparin net sales of \$176 million, which was down from \$247 million for the first quarter 2011 due to loss of enoxaparin exclusivity. First quarter 2012 revenues also include \$0.6 million in amortization of the \$33 million payment received from the Baxter collaboration.

Research and development expenses for the first quarter of 2012 were \$18.6 million, compared to \$12.9 million for the same period in 2011. The increase was primarily due to increased headcount, laboratory and facility expenses to advance the company's development pipeline of complex generics, follow-on biologics, and novel drug candidates.

General and administrative expenses for the quarter ended March 31, 2012 were \$11.0 million, compared with \$8.3 million for the same period in 2011. The increase is primarily due to an increase of \$1.3 million in legal expenses related to enoxaparin litigation, an increase of \$1.0 million in stock-based compensation expense, as well as an increase of \$1.0 million of personnel and facilities-related expenses, offset by a decrease of \$0.8 million in enoxaparin related royalty expense.

At March 31, 2012, Momenta had \$382.3 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.

Financial Guidance

Momenta is today reiterating its guidance provided on February 9, 2012 for total operating expenses, excluding stock compensation and royalties payable to the Massachusetts Institute of Technology, and net of collaborative revenues, of approximately \$22 to \$28 million per quarter for 2012.

Conference Call Information

Management will host a conference call today, May 3, 2012 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 72247825. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through May 9, 2012. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 72247825.

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 May 17, 2012.

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, follow-on biologics and to the discovery and development of novel drugs.

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 March 31, 2012, our profitability, our expected product development milestones, our plans for future research and development investment, and our other product development 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 Annual Report on Form 10-K for year ended December 31, 2011 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.

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.

MOMENTA PHARMACEUTICALS, INC.
Unaudited, Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2012	December 31, 2011
Assets		
Cash and marketable securities	\$ 382,261	\$ 348,438
Accounts receivable	22,372	28,171
Restricted cash	17,500	17,500
Other assets	32,333	26,800
Total assets	<u>\$ 454,466</u>	<u>\$ 420,909</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 22,625	\$ 16,028
Deferred revenue, net of current portion	29,518	1,608
Other liabilities	131	195
Stockholders' equity	402,192	403,078
Total liabilities and stockholders' equity	<u>\$ 454,466</u>	<u>\$ 420,909</u>

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

	Three Months Ended March 31,	
	2012	2011
Collaboration revenues:		
Product revenue	\$ 22,029	\$ 75,761
Research and development revenue	2,199	2,411
Total collaboration revenue	24,228	78,172
Operating expenses:		
Research and development*	18,562	12,943
General and administrative*	10,955	8,310
Total operating expenses	29,517	21,253
Operating (loss) income	(5,289)	56,919
Other income (expense):		
Interest income	307	128
Interest expense	—	(41)
Total other income	307	87
Net (loss) income	\$ (4,982)	\$ 57,006
Comprehensive (loss) income	\$ (4,875)	\$ 56,953
Net (loss) income per share:		
Basic	\$ (0.10)	\$ 1.15
Diluted	\$ (0.10)	\$ 1.13
Weighted average shares outstanding:		
Basic	50,240	49,532
Diluted	50,240	50,334

*Includes the following share-based compensation expense:

Research and development	\$ 1,355	\$ 837
General and administrative	\$ 1,899	\$ 929

CONTACT:

Lora Pike
Momenta Pharmaceuticals, Inc.
lpike@momentapharma.com
(617) 395-5189

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