MOMENTA PHARMACEUTICALS INC
Form 8-K
April 30, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): **April 30, 2008 (April 28, 2008)**

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-50797**	**04-3561634**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

675 West Kendall Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	(Zip Code)

(617) 491-9700

(Registrant s telephone number, including area code)

Not applicable

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On April 29, 2008, Momenta Pharmaceuticals, Inc., a Delaware corporation (the Company), announced that its collaboration partner, Sandoz Inc. (Sandoz), a division of Novartis, had received a letter from the U.S. Food and Drug Administration (the FDA) on April 28, 2008, providing guidance with respect to the Abbreviated New Drug Application (ANDA) for M-Enoxaparin Sodium Injection, the Company s technology-enabled generic version of Lovenox®.

Earlier this year, the Company and Sandoz submitted a proposal to the FDA for addressing the potential immunogenicity of M-Enoxaparin, in response to the FDA s letter of November, 2007. On April 28, 2008, the FDA responded to the proposal and provided additional guidance which indicated general concurrence with the Company s approach and proposal. The FDA also requested additional data from *in vitro* and *in vivo* tests, the testing of additional samples for tests previously proposed and additional information regarding certain of the methods proposed. The FDA has not requested human clinical trials at this time; however, there can be no assurances that the FDA will not require such studies in the future.

The Company and Sandoz are still evaluating the FDA s guidance, but, based on a preliminary assessment, the Company and Sandoz anticipate that they will be able to submit an amendment to the M-Enoxaparin ANDA containing the requested additional data during the third quarter of 2008.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements.

Forward-looking statements can be identified by terminology such as anticipate, believe, could, could increase the likelihood, estimate, exp intend, is planned, may, should, will, will enable, would be expected, look forward, may provide, would or similar terms, var terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors including those risks, uncertainties and factors referred to in the Company s Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission under the section Risk Factors, 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 Current Report on Form 8-K as of this date and assumes no obligations to update the information included herein or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

SIGNATURE

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.

Date: April 30, 2008

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