

MOMENTA PHARMACEUTICALS INC  
Form 8-K  
June 28, 2007

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## 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): **June 27, 2007**

## 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)

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

**Not Applicable**

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

## Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 8-K

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))
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### Item 8.01 Other Events

Momenta Pharmaceuticals, Inc. s (the Company ) most advanced product candidate, M-Enoxaparin is designed to be a technology-enabled generic version of Lovenox® (enoxaparin sodium injection). An Abbreviated New Drug Application ( ANDA ) for M-Enoxaparin was submitted by Sandoz N.V. and Sandoz Inc. (together referred to as Sandoz ) to the U.S. Food and Drug Administration ( FDA ) on August 29, 2005, seeking approval to market M-Enoxaparin in the United States. The Company previously estimated that the FDA s review of the ANDA for M-Enoxaparin would be completed approximately 18 to 24 months following the ANDA s submission.

Due to a change in the projected timing of certain activities required for the completion of the FDA s review of the ANDA for M-Enoxaparin, the Company believes that completion of the review of the ANDA for M-Enoxaparin will likely extend beyond its prior guidance of 18 to 24 months following submission. The Company is not providing further guidance on its projected timing of completion of the FDA s review, but the Company believes that the FDA s ongoing review continues to progress satisfactorily. However, any FDA approval of a generic drug for commercial distribution depends on a variety of factors, which involve risks and uncertainties. Our successful development and commercialization of M-Enoxaparin, in collaboration with Sandoz, depends on a number of factors, including: using our technology to successfully demonstrate to the FDA that M-Enoxaparin is therapeutically equivalent to Lovenox; meeting any other FDA requirements for marketing approval; and successfully manufacturing M-Enoxaparin in a consistent, cost-effective and reproducible manner and at a commercial scale.

### 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, expect, intend, is planned, may, should, will, will enable, would be expected, look forward, may provide, would or similar terms, variations 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 Quarterly Report on Form 10-Q for the quarter ended March 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: June 27, 2007

By:

/s/ Richard P. Shea  
Richard P. Shea  
Chief Financial Officer

3

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