MOMENTA PHARMACEUTICALS INC
Form 8-K
August 08, 2006

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) August 8, 2006 (August 8, 2006)

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in 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)

(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 August 8, 2006, Momenta Pharmaceuticals, Inc., a Delaware corporation (the Company), learned that Aventis Pharmaceuticals Inc. and Aventis Pharma S.A. (collectively, Sanofi-Aventis), the holder of the New Drug Application for Lovenox®, a widely prescribed low molecular weight heparin, initiated litigation against Sandoz Inc. relating to the paragraph IV certification contained in the Abbreviated New Drug Application (ANDA) filed by Sandoz Inc. seeking approval to market M-Enoxaparin in the United States.

The Company s most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox. In 2003, the Company formed a collaboration with Sandoz N.V. and Sandoz Inc. (collectively, Sandoz), affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin (the 2003 Sandoz Collaboration). In accordance with the 2003 Sandoz Collaboration, an ANDA was submitted by Sandoz to the FDA for M-Enoxaparin on August 29, 2005. The ANDA for M-Enoxaparin was subsequently amended by Sandoz to include a paragraph IV certification.

Since the Company s inception, all of the Company s revenues have been derived from the 2003 Sandoz Collaboration and primarily consist of amounts earned by the Company for reimbursement by Sandoz of research and development services and development costs for M-Enoxaparin.

In 1984, Congress enacted the Hatch-Waxman Act to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. Under the Hatch-Waxman Act, for each patent listed in the Orange Book for the relevant branded drug, an ANDA applicant must certify one of the following claims: (1) that such patent information has not been filed; (2) that such patent has expired; (3) the proposed drug will not be marketed until expiration of the patent; or (4) that either the proposed generic drug does not infringe the patent or the patent is invalid, otherwise known as paragraph IV certification.

If an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification and provides the patent holder with a 45-day window, during which it may bring suit against the applicant for infringement. If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of: (1) 30 months from the patent holder s receipt of the notice; or (2) the issuance of a non-appealable court decision finding the patent invalid or not infringed.

If the patent is found to be infringed by the filing of the ANDA, the patent holder may seek an injunction to block the launch of the generic product until the patent expires. Often more than one company will file an ANDA that includes a paragraph IV certification. However, the Hatch-Waxman Act provides that any subsequent ANDA applications will not be approved until 180 days after the earlier of: (1) the date of the first commercial marketing of the first-filed ANDA applicant s generic drug; or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable or not infringed. The Hatch-Waxman Act therefore effectively grants the first ANDA holder to have its ANDA accepted for review by the FDA with 180 days of marketing exclusivity for the generic product.

Under the 2003 Sandoz Collaboration, Sandoz has agreed to indemnify the Company and the Company s collaborators involved in the M-Enoxaparin program, for any losses resulting from, among other things, any litigation by third parties, including Sanofi-Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the FDA s Orange Book for Lovenox. In the event that patent litigation expenses exceed a specified amount, Sandoz is permitted to offset a portion of the excess against profit-sharing amounts, royalties and the commercial milestone payments set forth in the 2003 Sandoz Collaboration. To the extent that any losses result from a third party claim for which the Company is obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify the Company.

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: August 8, 2006