NOVEN PHARMACEUTICALS INC
Form 8-K
February 26, 2004

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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): February 26, 2004

Noven Pharmaceuticals, Inc.

11960 S.W. 144TH Street, Miami, Florida 33186

305-253-5099

Incorporated under the laws of the	Commission File Number	I.R.S. Employer Identification Number
State of Delaware	**0-17254**	**59-2767632**

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Item 5. Other Events

On February 26, 2004, Noven Pharmaceuticals, Inc. (Noven) entered into an exclusive license agreement with Endo Pharmaceuticals, Inc. (Endo) pursuant to which Noven granted Endo the right to market its fentanyl transdermal system in the United States and Canada. Noven retained all rights to the fentanyl patch outside of the U.S. and Canada, and Noven is exploring strategies to commercialize the product in other territories. Noven earned an up-front payment of $8.0 million from Endo upon the signing of the agreement. The agreement provides that, upon Endo s first commercial sale of the fentanyl patch, Noven is entitled to receive an additional milestone payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Under a long-term supply agreement entered into between the parties, Noven will manufacture and supply the product at its cost and will share in Endo s profit from U.S. product sales.

Under the terms of the transaction, Noven remains responsible for securing final regulatory approval for its fentanyl transdermal system. The agreement provides that Endo may terminate the agreement, and thereby avoid its obligation to launch the product, if launch is delayed either because of a delayed FDA approval or Noven s failure to supply Endo with its launch requirements after approval. Endo s termination right will be triggered if such a delay results in additional generic competition beyond that currently expected by the parties. The earliest that this right could be triggered under the agreement is May 2005. In the event of such a termination, rights to the fentanyl patch would return to Noven.

The agreement provides that Endo is responsible for seeking regulatory approval to market the product in Canada. If such efforts are successful, Noven will supply product for sale in Canada on a cost-plus basis, with no royalty or profit sharing arrangement.

In addition to the fentanyl license, Noven has established a collaboration with Endo to identify and develop new transdermal therapies. Of the $8.0 million received at signing, $1.5 million will be allocated to fund feasibility studies undertaken by Noven to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

Noven s press release announcing the transaction, a copy of which is filed as Exhibit 99.1, includes cautionary factors related to the Endo transaction and is incorporated in to this Item 5 by reference.

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Item 7. Exhibits

(c) Exhibits.

99.1 Press release dated November 26, 2004 announcing the license of Noven Pharmaceuticals, Inc. s transdermal fentanyl system to Endo Pharmaceuticals Inc.

99.2 Press release dated February 26, 2004 announcing the financial results of Noven Pharmaceuticals, Inc. for the year ended December 31, 2003.

Item 12. Results of Operations and Financial Condition

On February 26, 2004, Noven issued a press release announcing its financial results for the year ended December 31, 2003. This press release, a copy of which is attached hereto as Exhibit 99.2, is furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the Exchange Act) or incorporated by reference into a filing under the Securities Act of 1933 or the Exchange Act.

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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 thereunto duly authorized.

NOVEN PHARMACEUTICALS, INC.

/s/ Jeffrey F. Eisenberg
Jeffrey F. Eisenberg
Vice President, General Counsel and
Corporate Secretary

Date: February 26, 2004

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INDEX TO EXHIBITS

Exhibit No.	Description
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