NOVADEL PHARMA INC
Form 8-K
August 06, 2007

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) August 1, 2007

NOVADEL PHARMA INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-32177**	**22-2407152**
(State or other jurisdiction of incorporation or organization)	**(Commission File No.)**	**(I.R.S. Employer Identification No.)**

25 Minneakoning Road

Flemington, New Jersey 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

(Registrant s telephone number, including area code)

N/A

(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 1.01 Entry into a Material Definitive Agreement.

On July 31, 2007, NovaDel Pharma Inc., a Delaware corporation (the Company), entered into a Product Development and Commercialization Sublicense Agreement with HANA Biosciences, Inc., a Delaware corporation (HANA), and PAR Pharmaceuticals, Inc., a Delaware corporation (PAR) (the Sublicense Agreement), pursuant to which HANA granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to PAR to develop and commercialize Zensana , the Company s oral spray version of ondansetron, a leading anti-emetic for preventing chemotherapy-induced nausea and vomiting. In connection therewith, the Company and HANA amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana (the Amended and Restated License Agreement) to coordinate certain of the terms of the Sublicense Agreement.

Under the terms of the Sublicense Agreement, PAR is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada, with the Company able to collaborate on development in certain instances. The Company retains its rights to Zensana outside of the United States and Canada. Under the terms of the Sublicense Agreement, HANA is entitled to certain milestone payments from PAR upon achievement of certain developmental and commercialization events. HANA is also entitled to certain royalty payments from PAR based on the level of annual net sales of Zensana, which royalty payments are to be passed through directly to the Company in their entirety. Consistent with the original License and Development Agreement, as amended, the Company is entitled under the Amended and Restated License Agreement to a milestone payment from HANA upon approval by the U.S. Food and Drug Administration of Zensana and double-digit royalties on net sales of Zensana. The royalty rate varies based on the level of annual net sales of Zensana, but ranges from 25% - 15%. The Company s right to receive royalties from HANA for the sale of Zensana expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to Zensana in that country, and (b) twenty (20) year anniversary of the execution of the Sublicense Agreement and Amended and Restated License Agreement. In addition, under the terms of the Amended and Restated License Agreement, HANA relinquished its right to reduced royalty rates to the Company until such time as HANA had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana or payments or other fees from a sublicense and the Company agreed to surrender for cancellation all 73,121 shares of the HANA common stock acquired by the Company in connection with execution of the original License Agreement.

Under the Sublicense Agreement, PAR is responsible for the development and re-filing of the New Drug Application for Zensana in the United States. PAR has agreed to bear all expenses related to U.S. development activities, with the Company being reimbursed for any collaborative development activities undertaken by the Company. Each of the Sublicense Agreement and the Amended and Restated License Agreement, unless earlier terminated, shall expire, on a country-by-county basis upon the later of: (i) expiration of the last-to-expire issued patent that includes at least one valid claim, and (ii) the twenty (20) year anniversary of the execution of the Sublicense Agreement and the Amended and Restated License Agreement

The foregoing is a summary of the material terms of the Sublicense Agreement and Amended and Restated License Agreement and does not purport to be complete. You should read the complete Sublicense Agreement and Amended and Restated License Agreement which shall be attached as an exhibit to the Company s next Quarterly Report on Form 10-Q.

Item 1.02 Termination of a Material Definitive Agreement.

On July 31, 2007, the Company and PAR agreed to terminate the Development, Manufacturing and Supply Agreement, dated July 28, 2004 (the DMS Agreement) relating to NitroMist , the Company s product candidate for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. Under the DMS Agreement, PAR had exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada, with the Company entitled to royalty payments based upon a percentage of net sales. The Company is currently investigating strategic partners for the commercialization of NitroMist.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of NovaDel Pharma Inc. dated August 1, 2007, titled NovaDel Announces Sublicense Agreement for Zensana - Partnership with Par Pharmaceuticals Provides Best Strategic Path for Promising Drug.

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.

NovaDel Pharma Inc.

By:	/s/ Michael E. Spicer
Name:	Michael E. Spicer
Title:	Chief Financial Officer and Corporate Secretary

Date: August 6, 2007