NOVADEL PHARMA INC
Form 8-K
March 13, 2006

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) March 9, 2006

NOVADEL PHARMA INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-32177**	**22-2407152**
(State or other jurisdiction of incorporation)	**(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 7.01. Regulation FD Disclosure.

On March 9, 2006, NovaDel Pharma Inc. (the Company) issued a press release to announce that Hana Biosciences, Inc. (Hana), the Company s partner in the development and commercialization of Zensana (ondansetron oral spray), has successfully completed all clinical trials required for FDA registration under section 505(b)(2), as further discussed in Item 8.01 below, which is incorporated by reference herein. Such press release is being furnished pursuant to this Item 7.01 of this Current Report on Form 8-K and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 8.01. Other Events.

As discussed in Item 7.01, the Zensana clinical development program is the largest clinical program conducted to date for a product using the Company s proprietary oral transmucosal spray technology. The ondansetron program consisted of 4 clinical pharmacokinetic studies. The studies established bioequivalence of Zensana to the Zofran® tablet, evaluated the pharmacokinetic profile of Zensana after administration of multiple doses and investigated food and water effects on the pharmacokinetics of Zensana . Hana reported that Zensana 8 mg dose is bioequivalent to the 8 mg ondansetron (Zofran®) tablet, and can be administered in multiple doses.

Zensana demonstrated faster initial absorption when compared to the Zofran® tablet. The median time to detectable ondansetron levels after drug administration was 15 minutes for Zensana versus 30 minutes for Zofran® tablets. The detected difference was highly statistically significant ($p<0.01$). Data from the 4 completed studies indicate that administration of Zensana was well tolerated and did not generate any unexpected adverse events. Details of these results will be presented by Hana at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in June.

With these clinical studies complete, Hana confirmed its plan to submit the NDA in 2006 and targets a US commercial launch in 2007.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1. Press release dated March 9, 2006, titled NovaDel Announces That Ondansetron Oral Spray Has Met The Key Regulatory Requirement Of Bioequivalence.

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/ Jean W. Frydman

Name: Jean W. Frydman
Title: Vice President and General Counsel

Date: March 13, 2006

EXHIBIT INDEX

Exhibit	Description
99.1	Press release dated March 9, 2006, titled NovaDel Announces That Ondansetron Oral Spray Has Met The Key Regulatory Requirement Of Bioequivalence.