NOVADEL PHARMA INC
Form 8-K
October 18, 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) October 16, 2006

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 7.01. Regulation FD Disclosure

On October 16, 2006, NovaDel Pharma Inc., a Delaware corporation (the Company), issued a press release to announce that the Company would present at the BIO InvestorForum 2006 Conference on October 19, 2006, in San Francisco, California. Dr. Jan Egberts, the Company s President and Chief Executive Officer, will present a corporate overview describing the Company, including an update on the Company s product pipeline. A copy of the Corporate Presentation which is the basis of Dr. Egberts October 19, 2006 presentation is attached hereto as Exhibit 99.1 and the full text of the press release is attached hereto as Exhibit 99.2. The Corporate Presentation is available on the Company s website at www.novadel.com.

The information furnished pursuant to this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 and 99.2, shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events

The Company now estimates its product candidates are expected to reach the market during the following calendar years: Zensana, 2007; NitroMist, 2007; Zolpidem, 2008; Sumatriptan, 2009; Tizanidine, 2009; and Ropinirole, 2009.

Additionally, on May 26, 2006, the Company announced that the Food and Drug Administration (the FDA) had accepted its submission regarding the New Drug Application for the Company s product candidate NitroMist as a complete response and, further, that the FDA indicated a target date of early November 2006 for action on the submission. The Company is now providing additional information that the FDA has indicated a target date of November 3, 2006 for action on the submission.

The Company is also providing additional information on planned pivotal studies for zolpidem oral spray and planned clinical studies for sumatriptan oral spray, including (1) a planned definitive pharmacokinetic study for zolpidem oral spray which is designed as a 4-arm crossover study in 32 healthy volunteers using 5 and 10 mg doses of zolpidem oral spray and Ambien® tablet to begin in January 2007 and a planned geriatric pharmacokinetic 2-arm crossover study in 16 healthy volunteers using 5 mg does of zolpidem oral spray and Ambien® tablet (the key endpoints for the planned zolpidem studies are area-under-the-curve (AUC), maximum drug concentration (Cmax), time to maximum drug concentration (Tmax) and other pharmacokinetic parameters); and (2) planned clinical studies for sumatriptan oral spray which includes a pilot efficacy study in 28 migraine sufferers which began in mid-August 2006 in India and is expected to be completed in December 2006 (the key parameters are time to substantial pain relief and percent of subjects experiencing substantial pain relief at 2 hours post-dosing) and one definitive pharmacokinetic study which is tentatively designed as a 5-arm crossover study in 32 healthy volunteers using 6 mg subcutaneous Imitrex®, 50 mg Imitrex® tablet, 5 mg nasal spray, 20 mg and 30 mg doses of sumatriptan oral spray (the key endpoints are the same as described above for the zolpidem pharmacokinetic studies).

The Company is updating its patent disclosure to reflect its current patent portfolio of 8 U.S. patents issued, 51 European patents issued, and 1 Canadian patent issued and over 80 applications pending in the U.S. and overseas.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Corporate Presentation which is the basis of presentation at October 19, 2006 BIO InvestorForum 2006 Conference

99.2 Press release dated October 16, 2006, titled NovaDel Pharma to Present at BIO InvestorForum 2006 Conference.

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

Date: October 18, 2006