NOVADEL PHARMA INC
Form 8-K
October 15, 2010

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 15, 2010

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.)

1200 Route 22 East, Suite 2000
Bridgewater, NJ 08807
(Address of principal executive offices) (Zip Code)

(908) 203-4640
(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 15, 2010, NovaDel Pharma Inc., a Delaware corporation (the "Company"), issued a press release to announce results from its Pilot Pharmacokinetic ("PK") Study and safety results comparing Duromist™, the Company's oral spray formulation of sildenafil citrate, to Viagra®, the tablet formulation of sildenafil citrate developed and marketed by Pfizer. The Company intends to review the results from the Pilot PK Study with the United Stated Food and Drug Administration to obtain guidance on defining definitive clinical trial requirements as a pathway to New Drug Application approval.

A copy of the press release is being furnished with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information set forth in this Item 7.01, including Exhibit 99.1, 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, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On October 15, 2010, the Company reported the following results from the Pilot PK Study.

Objectives of the Study

The Pilot PK Study was designed primarily to assess the relative bioavailability of one, two and three doses of 10 mg/0.12ml of Duromist™, compared to that of the 25 mg Viagra® tablet in healthy adult male subjects.

The secondary objective was to assess the relative safety of Duromist™ following single oral dose administration compared to that of 25 mg Viagra® tablets. Safety assessments included evaluation of changes in orthostatic hypotension, oral irritation, vital sign and electrocardiogram assessments.

Results of the Study

The preliminary study data demonstrated that 20 mg (or two sprays) of Duromist™ is bioequivalent to the 25 mg Viagra® tablet with respect to systemic exposure (AUC0-inf). The mean AUC0-inf for the 10 mg or one spray dose was approximately 40% of the 25 mg Viagra® tablet, as expected. The mean AUC0-inf for the 30 mg (or three spray) dose was approximately 40% higher than the 25 mg Viagra® tablet which is about 20% higher than expected. The increased systemic exposure (AUC) observed with the 20 and 30 mg oral spray doses compared to the Viagra® tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (Cmax) than that of the 25 mg Viagra® tablet was observed with the 20 mg oral spray dose. The Tmax (or time point at Cmax) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra® tablet (1.10 and 1.04 hours, respectively).

N-desmethylsildenafil is an active metabolite of sildenafil formed as a result of first-pass liver metabolism. The rate of metabolite formation with the oral spray is different than that observed with the reference tablet and is consistent with transmucosal absorption.

Duromist™ demonstrated an excellent safety profile and was well tolerated in the Pilot PK Study. There was no evidence of oral irritation and no adverse events were reported after administration of up to three doses of Duromist™. Vital signs were within normal range and there were no episodes of orthostatic hypotension observed in any of the four treatment periods. No changes were observed in the subjects' electrocardiograms in any of the four treatment periods.

About the Study

This was a single-center, open-label, single-dose, randomized, four-period, four-treatment crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24. All subjects were required to stay at the clinical site for at least 24 hours after each treatment period.

The Duromist™ oral spray test article used in this study was supplied as 10 mg/120 µl sildenafil per spray actuation. The 25 mg sildenafil citrate tablet was supplied from commercial sources as Viagra® from Pfizer Inc.

Measurements

Pharmacokinetic: The following parameters were used in the data analysis for plasma sildenafil and N-desmethylsildenafil concentrations: AUC0-t, The area under the plasma concentration versus time curve, from time 0 to the last measurable concentration; AUC0-inf, Calculated as the sum of the AUC0-t plus the ratio of the last measurable plasma concentration to the elimination rate constant; AUC0-t/AUC0-inf, The ration of the AUC0-t to AUC0-inf; Cmax, The maximum measured plasma concentration observed; Tmax, defined as the time point of Cmax; Kel, The apparent first-order terminal elimination rate constant; T1/2, The apparent first-order terminal elimination half-life; Ratio Metabolite/Parent, The ratio of the metabolite/parent assessed at each concentration, Cmax, AUC0-t, AUC0-inf.

Safety: Vital signs (supine and standing); Electrocardiogram at screening and post-dose; Changes in physical examinations, including oral soft tissue examinations at and after each oral spray dosing, laboratory parameters and adverse events.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of NovaDel Pharma Inc. dated October 15, 2010, titled "NovaDel Pharma Inc. Announces Positive Data from Pilot Pharmacokinetic Study Comparing Duromist™ (sildenafil citrate oral spray) to Viagra® Tablet."

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/ STEVEN B. RATOFF
Name:	Steven B. Ratoff
Title:	President and Chief Executive Officer

Date: October 15, 2010