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NOVADEL PHARMA INC
Form 8-K
November 01, 2004

UNITED STATES
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

SEPTEMBER 30, 2004
Date of Report (Date of earliest event reported)

NOVADEL PHARMA INC.
(Exact name of Registrant as specified in its charter)

| | | |
|---|--------------------------|---|
| DELAWARE | 000-23399 | 22-2407152 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification Number) |

25 MINNEAKONING ROAD
FLEMINGTON, NEW JERSEY 08822
(Address of principal executive offices)

(908) 782-3431
(Registrant's telephone number, including area code)

(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:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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 October 27, 2004, NovaDel Pharma Inc. (the "Company"), entered into a License and Development Agreement (the "Agreement") with Hana Biosciences, Inc. ("Hana"), whereby Hana will develop and market the Company's lingual spray version of ondansetron, the most widely prescribed anti-emetic for preventing chemotherapy-induced nausea and vomiting. Under the Agreement, Hana has exclusive rights to market, sell and distribute the Company's ondansetron lingual spray in the United States and Canada. Under the Agreement, the Company is entitled to receive milestone development payments and double-digit royalties

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on sales of the lingual spray version of ondansetron.

Pursuant to the terms of the Agreement, Hana purchased 400,000 shares of newly issued common stock, par value \$.001 per share, of the Company at a per share purchase price equal to \$2.50 per share, and Hana issued to the Company \$500,000 worth of shares of common stock of Hana (the number of shares having been calculated based on the average price of Hana's common stock during the 10 business days prior to the effective date of the Agreement). Pursuant to a pre-emptive right granted to the investors in the Company's private offering of shares of the Company's common stock in April and May 2003, such investors have the right, but not the obligation, to purchase approximately 900,000 additional shares of the Company's common stock at the same per share purchase price paid by Hana. The Company does not expect any of such investors to exercise such right.

Lindsay A. Rosenwald, M.D., a significant shareholder of the Company, may be deemed to be an affiliate of both parties to the Agreement. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to the Agreement to both parties from time to time.

The Company's press release announcing the Agreement is attached hereto as Exhibit 99.1.

ITEM 4.02 NON-RELIANCE ON PREVIOUSLY ISSUED FINANCIAL STATEMENTS OR A RELATED AUDIT REPORT OR COMPLETED INTERIM REVIEW

In connection with the preparation of the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2004, the Company's independent registered public accounting firm, J.H. Cohn LLP ("J.H. Cohn"), brought to the attention of the Company that certain of the Company's issued and outstanding stock options might need to be subject to variable accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expense might need to be recognized in the Company's previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions Involving Stock Compensation--an interpretation of APB Opinion No. 25" (Issue Date 3/00).

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As of October 25, 2004, the Board of Directors of the Company concluded that it was possible that the Company's financial statements for all of the Company's fiscal periods since January 15, 2002, should no longer be relied upon because of the impact of such variable accounting treatment. Under variable option accounting, compensation expense is increased or decreased as a result of changes in the market price of the Company's common stock. The Company's management is in the process of reviewing the adjustments with its Board of Directors and its current and previous independent registered public accounting firms, each of whom agreed with the Company's decision to restate its results of operations for the fiscal years ended July 31, 2002, and July 31, 2003, and for the Company's quarterly results in fiscal year 2004. The Company has rescinded the applicable option exercise provisions that resulted in the variable option accounting treatment in the Company's financial statements. Upon completion of such review, the Company intends to restate its financial statements, as and to the extent required.

As previously reported, prior to November 26, 2003, the Company used a different outside independent registered public accounting firm for its filings with the Securities and Exchange Commission. That firm no longer performs independent audits. The Company's present registered independent registered public accounting firm is J.H. Cohn.

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The Audit Committee of the Company's Board of Directors, Dr. William Hamilton and Mr. Robert G. Savage, as well as the remainder of the Board of Directors, Dr. Lawrence Kessel, Dr. Charles Nemeroff, Mark Rachesky and Gary A. Shangold, M.D., the Company's President and Chief Executive Officer, as well as Jean W. Frydman, the Company's Secretary, Vice President and General Counsel, discussed with J.H. Cohn the matters disclosed in this Item 4.02.

ITEM 5.02 DEPARTURE OF DIRECTORS OR PRINCIPAL OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF PRINCIPAL OFFICERS

Effective September 30, 2004, Donald J. Deitman resigned from the position of Chief Financial Officer of the Company. Gary A. Shangold, M.D., the Company's President and Chief Executive Officer will be the Company's interim principal financial officer.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits

99.1 Press release dated October 27, 2004.

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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 hereunto duly authorized.

NOVADEL PHARMA INC.

By: /s/ Gary A. Shangold

Name: Gary A. Shangold, Ph.D.

Title: President and Chief Executive Officer

Date: November 1, 2004

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