

NOVADEL PHARMA INC  
Form 10-Q  
December 15, 2005  
**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended October 31, 2005**

OR

**[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

*COMMISSION FILE NO. 001-32177*

**NOVADEL PHARMA INC.**

(Name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of  
incorporation or organization)

22-2407152

(I.R.S. Employer Identification  
No.)

Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

**25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822**

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant's telephone number, including area code

Indicate by check mark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined by Rule 12b-2 of the Exchange Act). Yes  No .

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes  No

As of December 1, 2005, the issuer had 40,647,318 shares of Common Stock, \$.001 par value, outstanding.

---

**NOVADEL PHARMA INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2005**

**TABLE OF CONTENTS**

	PAGE
<b>PART I- Financial Information</b>	
Item 1. Financial Statements.	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.	13
Item 3. Quantitative and Qualitative Disclosure about Market Risk.	16
Item 4. Controls and Procedures.	16
<b>PART II-Other Information</b>	
Item 1A. Risk Factors	17
Item 5. Other Information	19
Item 6. Exhibits	20



**Safe harbor statements under the private securities litigation reform act of 1995**

This Current Report on Form 10-Q includes forward-looking statements, including statements regarding NovaDel Pharma Inc.'s (the Company or NovaDel) expectations, beliefs, intentions or strategies for the future and the Company's internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company's views as of the date they are made with respect to future events and financial performance. In particular, the Management's Discussion and Analysis of Financial Condition and Results of Operation section in Part I, Item 2 of this Quarterly Report includes forward-looking statements that reflect the Company's current views with respect to future events and financial performance. The Company uses words such as expect, anticipate, believe, intend and similar expressions to identify forward-looking statements. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. A number of important risks and uncertainties could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company's financial condition; the progress of the Company's research and development; clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in the Company's clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company's ability to obtain additional required financing to fund its research programs; the Company's ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the FDA approvals in connection with the conduct of the Company's clinical trials and the marketing of the Company's products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; the risks related to the Company's internal controls and procedures; and the risks identified under the section entitled Risk Factors following Item 5 in Part II of the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005, and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time. Part II, Item IA of this Quarterly Report includes an update to the risk factors that have materially changed from the risk factors included in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005.

**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NOVADEL PHARMA INC.****CONDENSED BALANCE SHEETS****AS OF OCTOBER 31, 2005 (UNAUDITED) AND JULY 31, 2005**

	<b>October 31, 2005</b> <b>(unaudited)</b>	<b>July 31, 2005</b> <b>(Note 2)</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,660,000	\$4,680,000
Short-term investments	2,395,000	3,543,000
Accounts receivable from related parties, net of allowances of \$54,000.	123,000	108,000
Inventories	543,000	549,000
Prepaid expenses and other current assets	570,000	306,000
Total Current Assets	6,291,000	9,186,000
Property and equipment, net	2,973,000	2,991,000
Other assets	351,000	351,000
Investment in marketable equity security	365,000	500,000
<b>TOTAL ASSETS</b>	<b>\$9,980,000</b>	<b>\$13,028,000</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable-trade	\$619,000	\$1,179,000
Accrued expenses and other current liabilities	959,000	1,064,000
Current portion of deferred revenue	162,000	162,000
Total Current Liabilities	1,740,000	2,405,000
Non-current portion of deferred revenue	2,633,000	2,674,000
Total Liabilities	4,373,000	5,079,000
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$.01 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, \$.001 par value:		
Authorized 100,000,000 shares, Issued 40,622,318 and 40,597,318 shares at		
October 31, 2005 and July 31, 2005, respectively	41,000	41,000
Additional paid-in capital	42,673,000	42,305,000
Accumulated deficit	(36,966,000)	(34,391,000)
Accumulated other comprehensive loss	(135,000)	)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)

Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Total Stockholders' Equity	5,607,000	7,949,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$9,980,000	\$13,028,000

See accompanying notes to condensed financial statements.

## NOVADEL PHARMA INC.

## CONDENSED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended October 31, 2005	2004
License Fees and Milestone Fees Earned from Related Parties	\$41,000	\$ 19,000
Consulting Revenues from Related Parties	109,000	99,000
Total Revenues	150,000	118,000
Research and Development Expenses	897,000	660,000
Consulting, Selling, General and Administrative Expenses	1,871,000	1,736,000
Total Expenses	2,768,000	2,396,000
Loss From Operations	(2,618,000 )	(2,278,000 )
Interest Income	43,000	22,000
Net Loss	\$(2,575,000 )	\$ (2,256,000 )
Basic and Diluted Loss Per Common Share	\$ (.06 )	\$ (.07 )
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Share	40,606,000	33,100,000

See accompanying notes to condensed financial statements.





**NOVADEL PHARMA INC.**

**CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY**

**FOR THE THREE MONTHS ENDED OCTOBER 31, 2005**

**(UNAUDITED)**

	Common Stock				Accumulated Other Comprehensive Loss	Treasury Stock	Total Stockholders Equity
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit			
BALANCE, July 31, 2005	40,597,318	\$41,000	\$42,305,000	\$ (34,391,000 )	\$ -	\$ (6,000 )	\$ 7,949,000
Stock-based compensation expense			350,000				350,000
Stock issued for options exercised	25,000		18,000				18,000
Comprehensive loss:							
Unrealized loss on investment in marketable equities security					(135,000 )		(135,000 )
Net loss				(2,575,000 )			(2,575,000 )
Total comprehensive loss							(2,710,000 )
BALANCE, October 31, 2005	40,622,318	\$41,000	\$42,673,000	\$ (36,966,000 )	\$ (135,000 )	\$ (6,000 )	\$ 5,607,000

See accompanying notes to condensed financial statements.

## NOVADEL PHARMA INC.

## STATEMENTS OF CASH FLOWS

FOR THREE MONTHS ENDED OCTOBER 31, 2005 AND 2004

(UNAUDITED)

	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (2,575,000)	\$ (2,256,000)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	350,000	
Impact of variable plan accounting		29,000
Depreciation and amortization	103,000	107,000
Changes in operating assets and liabilities:		
Accounts receivable from related parties	(15,000)	65,000
Inventories	6,000	
Prepaid expenses and other current assets	(264,000)	(26,000)
Accounts payable trade	(560,000)	34,000
Accrued expenses and other current Liabilities	(105,000)	29,000
Deferred revenue	(41,000)	2,095,000
Net cash provided by (used in) operating activities	(3,101,000)	77,000
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(85,000)	(513,000)
Purchase of investments	(1,300,000)	(4,280,000)
Maturities of investments	2,448,000	3,811,000
Net cash provided by (used in) investing activities	1,063,000	(982,000)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Cash received from options exercised	18,000	
Proceeds from shares of common stock issued to Hana Biosciences, Inc.		636,000
Payments of capitalized lease obligations		(62,000)
Net cash provided by financing activities	18,000	574,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,020,000)	(331,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,680,000	2,166,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 2,660,000	\$ 1,835,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Investment in Hana Biosciences, Inc. common		
stock received in connection with license agreement	\$	\$ 500,000

See accompanying notes to condensed financial statements.

7

---

**NOVADEL PHARMA INC.**

**NOTES TO FINANCIAL STATEMENTS (UNAUDITED)**

**NOTE 1 - NATURE OF THE BUSINESS**

NovaDel Pharma Inc. (the Company) is engaged in the development of novel application drug delivery systems for presently marketed prescription, over-the-counter (OTC) and veterinary drugs. The Company's patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Currently, the Company has six patents which have been issued in the U.S. and seven patents which have been issued outside of the U.S. Additionally, the Company has over 120 patents pending around the world. The Company's proprietary delivery system potentially enhances and greatly accelerates the onset of the therapeutic benefits within minutes of administration. The Company's development efforts for its proprietary novel drug delivery system are concentrated on making such system available for drugs that are already available and proven in the marketplace. In addition to increasing the bioavailability of a drug by avoiding metabolism by the liver before entry into the bloodstream, the Company believes that its proprietary drug delivery system could offer the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iii) improved dosage reliability; (iv) allowing medication to be taken without water; and (v) improved patient convenience and compliance.

The Company has identified six priority products for development, namely nitroglycerin, sumatriptan, alprazolam, zolpidem, ondansetron and propofol. The Company also has identified a number of other development initiatives which are currently less of a priority than the Company's six priority programs.

Through October 31, 2005, the Company has entered into strategic license agreements with (i) Manhattan Pharmaceuticals, Inc. (Manhattan), in connection with propofol, (ii) Velcera Pharmaceuticals, Inc. (Velcera), in connection with veterinary applications for currently marketed veterinary drugs, (iii) Par Pharmaceutical, Inc. (Par), for the marketing rights in the United States and Canada for the Company's nitroglycerin oral spray, and (iv) Hana Biosciences Inc. (Hana), for the marketing rights in the United States and Canada for the Company's ondansetron oral spray.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX USA, Ltd. (INyX), whereby INyX will manufacture and supply the Company's nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX will be the exclusive provider substantially worldwide of the nitroglycerin lingual spray to the Company.

The Company has not entered into any other material development arrangements with any pharmaceutical companies.

**NOTE 2 - BASIS OF PRESENTATION AND LIQUIDITY**

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

The balance sheet at July 31, 2005, the end of the preceding fiscal year, has been derived from the audited balance sheet contained in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005, and is presented for comparative purposes. All other financial statements are unaudited. The condensed financial statements are presented on the basis of accounting principles generally accepted in the United States of America for interim financial statements. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect reported loss, financial position and various disclosures. Actual results could differ from those estimates. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the financial position, results of operations and cash flows for all periods presented, have been made in the interim financial statements. Results of operations for interim periods are not necessarily indicative of the operating results to be expected for a full fiscal year.

Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted in accordance with the published rules and regulations of the Securities and Exchange Commission. The condensed financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005.

The Company has reported a net loss of \$2,575,000 for the three months ended October 31, 2005 and a net loss of \$2,256,000 for the three months ended October 31, 2004. As of October 31, 2005, the Company had working capital of \$4,551,000, cash and cash equivalents of \$2,660,000 and short-term investments of \$2,395,000. Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of its equity or debt securities or bridge loans to the Company from third party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Although we expect to have sufficient cash to fund our operations through fiscal 2006, we would have to significantly reduce the pace of our ongoing development of our six priority product candidates unless we obtain additional working capital. Given the current and desired pace of product development of our six priority product candidates, we estimate that we will need to raise additional capital during fiscal year 2006 in order to fully fund our development activities through July 31, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. If we are unable to raise additional capital in fiscal 2006, we will likely be forced to curtail our desired development activities, which will delay the development of our product candidates. There can be no assurance that such capital will be available to us on favorable terms or at all. Management of the Company believes that no later than the fiscal quarter ending October 31, 2006, it will be necessary for the Company to obtain additional financing and/or consummate a strategic alliance with a business partner. There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside the control of the Company. The Company may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

### **NOTE 3 INVENTORIES**

Inventories, consisting of raw materials, are carried at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method.

Inventories at October 31, 2005 and July 31, 2005 primarily consisted of raw materials related to the Company's nitroglycerin lingual aerosol product candidate. Through outsourcing to INyX, the Company is in the process of starting to make commercial quantities for this product candidate prior to the date that such product candidate may receive final U.S. Food and Drug Administration (FDA) marketing approval (i.e., pre-launch inventory). On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol). The Company believes that the FDA is likely to give final approval once the Company completes its previously agreed to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. If final approval of this product candidate is not received, or approval is not received timely compared to our estimates for product shelf-life, the Company will write-off the related amounts of pre-launch inventory in the period of that determination. If the Company had been required to write-off the \$543,000 and \$549,000 recorded as pre-launch inventory at October 31, 2005 and July 31, 2005, respectively, these amounts would have been considered by the Company to have been material to its operating results and are likely to be considered material if such write-offs are required in a subsequent period.

### **NOTE 4 CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS**

Cash equivalents include certificates of deposit and money market instruments purchased with original maturities of three months or less when purchased. Short-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit and U.S. Treasury securities with original maturities greater than three months and less than one year.

### **NOTE 5 - LOSS PER SHARE**

Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Loss per common share is computed pursuant to SFAS No. 128, Earnings Per Share. Basic loss per share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of October 31, 2005 and July 31, 2005, there were 28,059,000 and 26,212,000 common shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per share computation.



**NOTE 6 - STOCK-BASED COMPENSATION**

At October 31, 2005, the Company had three plans which allow for the issuance of stock options and other awards: the 1992 Stock Option Plan, the 1997 Stock Option Plan and the 1998 Stock Option Plan (the Plans). These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options (ISOs) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company's common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), which revises Accounting for Stock-Based Compensation, (SFAS 123) and supersedes Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, (APB 25). SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that begins after June 15, 2005. Under SFAS 123R, the pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

The Company has adopted the SFAS 123R effective August 1, 2005 and has selected the Black-Scholes method of valuation for share-based compensation. The Company has adopted the modified prospective transition method which requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

Information with respect to stock option activity for the three months ended October 31, 2005 is as follows:

	<b>Outstanding Options Number of Options</b>	<b>Weighted Average Exercise Price</b>
	<b>(in thousands)</b>	
Balance at August 1, 2005	6,474	\$ 1.64
Additional shares reserved		
Grants	2,022	1.67
Exercises	(25 )	.75
Cancellations	(150 )	1.69
Balance at October 31, 2005	8,321	\$ 1.60

For grants during the three months ended October 31, 2005, the Company's weighted average assumptions used in determining fair value under the Black-Scholes model for expected volatility, dividends, expected term until exercise, and risk-free interest rate were 64%, 0%, 4 years and 4.05%, respectively. Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In the three months ended October 31, 2005, the Company recorded share-based compensation for options of approximately \$350,000 or \$.01 per share which is included in the Company's net loss for the period.

Prior to the adoption of SFAS 123R, the Company applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended, which were similar in most respects to SFAS 123R.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Compensation expense and credits were recorded through October 31, 2004 as a result of variable plan accounting due to cashless exercise provisions, which provisions were rescinded by the Board of Directors on October 20, 2004. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options of the Company, for which option exercise prices were modified from the original agreements.

The following table illustrates the pro forma effect on the Company's net loss and net loss per share as if the Company had adopted the fair-value-based method of accounting for stock-based compensation under SFAS 123 for the three months ended October 31, 2004:

	<b>Three Months Ended October 31, 2004</b>	
Net loss as reported	\$(2,256,000	)
Compensation expense resulting from variable plan accounting	29,000	
Total stock-based employee compensation expense using the fair value based method for all awards	(171,000	)
Pro forma net loss	\$(2,398,000	)
Basic and diluted net loss per common share:		
As reported	\$ (.07	)
Pro forma net loss	\$ (.07	)

The fair values of options granted in the three months ended October 31, 2004 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company's common stock of 66%, respectively, and an expected life of the options of five to ten years.

### **NOTE 7 RELATED PARTY TRANSACTIONS AND LICENSE AND DEVELOPMENT AGREEMENTS**

#### *License and Development Agreements with Related Parties*

In April 2003, the Company entered into a license and development agreement with Manhattan, a related party, for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first \$125,000 of which was partially received during June 2003. During the three months ended October 31, 2005 and 2004, the Company invoiced Manhattan approximately \$0 and \$65,000, respectively, for the Company's reimbursable expenses. In November 2003, the Company received \$375,000 from Manhattan for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company and related party. The license agreement is for the exclusive rights to the Company's proprietary oral spray technology in animals. In September 2004, the Company received \$1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received 529,500 shares of common stock of Velcera, approximately 15% of the outstanding shares at the time the shares were issued which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the three months ended October 31, 2005 and 2004, the Company invoiced Velcera approximately \$109,000 and \$0, respectively, for

reimbursable expenses.

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana, a related party, an exclusive license to develop and market the Company's oral spray version of ondansetron, an anti-emetic, in the United States and Canada. Pursuant to the terms of the agreement, in exchange for \$1,000,000, Hana purchased 400,000 shares of the Company's common stock at a per share price equal to \$2.50, a premium of \$.91 per share or \$364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana issued to the Company \$500,000 worth of common stock of Hana (73,121 shares based on a market value of \$6.84 per share). The proceeds received from Hana attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement.

11

---

*Other License and Development Agreements*

In July 2004, the Company entered into a licensing agreement with Par for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the United States and Canada. The Company has received \$250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement.

In November 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX will manufacture and supply the Company's nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX will be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it will be INyX's responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years.

**NOTE 8 INVESTMENT IN EQUITY SECURITY**

As explained in Note 7, in October 2004 as part of the license agreement with Hana, the Company received \$500,000 worth of common stock of Hana (73,121 shares based on a market value of \$6.84 per share). The Company is restricted from selling the shares for two years. Accordingly, at July 31, 2005 and in prior periods, the Company accounted for the investment using the cost method. At October 31, 2005, as the remaining restriction period is less than one year, the investment is considered to be a marketable equity security under the applicable accounting standards and is now recorded at its fair value and the \$135,000 unrealized loss is reflected in accumulated other comprehensive income. At October 31, 2005, the Company believes the decrease in the fair value of these shares to be temporary and no charge for impairment in the statement of operations is required.

**NOTE 9 SUBSEQUENT EVENTS**

On November 29, 2005 the Company entered into a Confidential Separation Agreement and General Release (the "Separation Agreement") and a Consulting Agreement (the "Consulting Agreement") with Gary Shangold, M.D. Dr. Shangold is the current Chief Executive Officer of the Company, who, as previously reported on September 2, 2005, has been notified by the Company that his employment agreement with the Company will not be extended at the end of its term on December 22, 2005.

Pursuant to the Separation Agreement, the Company will pay to Dr. Shangold a separation payment of \$150,000, pay Dr. Shangold's COBRA health insurance premium less any active employee contribution for up to one year from December 23, 2005, enter into the Consulting Agreement with Dr. Shangold, and permit Dr. Shangold's 100,000 stock options issued pursuant to the Nonqualified Stock Option and Incentive Stock Option Agreements, dated January 24, 2005, to vest as if Dr. Shangold were still an employee of the Company for as long as he provides consulting services to the Company pursuant to the Consulting Agreement and, in the event that the Consulting Agreement expires at the end of one year, to allow the 33,334 stock options that would otherwise vest on January 24, 2007, to vest on the expiration date of the Consulting Agreement. The Company will extend the post-termination exercise period applicable to Dr. Shangold's vested options (other than non-plan options) to a date that is 90 days after the termination of the Consulting Agreement. In exchange for the Company's agreement to provide the aforementioned consideration to Dr. Shangold, Dr. Shangold will release the Company from any and all claims he may have against the Company. In addition, Dr. Shangold will refrain from competition with the Company until the later of June 22, 2007 or 6 months after termination of the Consulting Agreement.

Pursuant to the Consulting Agreement, the Company will retain Dr. Shangold as an independent contractor to provide the Company with consulting services related to the drug regulatory and approval process. The Company will pay to Dr. Shangold an amount equal to \$2,500 per day worked, with a minimum guaranteed payment of \$25,000 per month in which he provides service to the Company regardless of whether the Company has requested his services for ten (10) days during the month, provided that the Company need not pay the entire \$25,000, but rather an amount for days worked at the per day rate, for any month in which the Company requested 10 or more days of service and Dr. Shangold was unavailable to provide his services after good faith efforts by both parties to accommodate the scheduling of services. In addition, the Company will reimburse Dr. Shangold for expenses incurred in the performance of these services. The Consulting Agreement will commence on

Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

December 23, 2005 and will continue for a period of 1 year, unless terminated earlier in accordance with the terms of the Consulting Agreement. The Consulting Agreement may be extended by mutual consent of the parties.

12

---

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### COMPANY OVERVIEW

We are engaged in the development of novel application drug delivery systems for presently marketed prescription, and veterinary drugs. Our patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and greatly accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on making it available for drugs that are already available and proven in the marketplace.

Since its inception, substantially all of the Company's revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. Although substantially all of the Company's revenues to date have been derived from its consulting business, the future growth and profitability of the Company will be principally dependent upon its ability to successfully develop its products and to market and distribute the final products either internally or with the assistance of a strategic partner.

Over the next fiscal year, the Company expects to continue to stay focused on its six priority products: nitroglycerin, sumatriptan, ondansetron, zolpidem, alprazolam and propofol.

Recent highlights include the following product development and business achievements:

Completed three pre-IND meetings with the FDA, including meetings for the following product candidates: (i) sumatriptan (Imitrex®); (ii) zolpidem (Ambien®); and (iii) ondansetron (Zofran®).

IND for ondansetron (Zofran®) filed by our partner, Hana Biosciences, Inc.

Addition of Chief Operating Officer who will assume the positions of President and Chief Executive Officer on December 23, 2005.

Nitroglycerin. On June 1, 2005, the Company received an approvable letter from the FDA regarding its NDA for NitroMist (nitroglycerin lingual aerosol). The Company believes that the FDA is likely to give final approval once the Company completes its previously agreed-to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. The Company is currently planning to complete its process validation commitments in the first calendar quarter of 2006; and, if this timeline is met, the Company may obtain final approval from the FDA in the second calendar quarter of 2006.

Sumatriptan. The Company had a pre-IND meeting with the FDA on August 10, 2005, and filed the IND in December 2005. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the sumatriptan oral spray product.

Zolpidem. The Company had a pre-IND meeting with the FDA on August 31, 2005 and anticipates filing the IND during the first quarter of calendar year 2006. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the zolpidem oral spray product.

Ondansetron. The Company's partner for this product, Hana Biosciences, filed the IND in November 2005. Subsequent to the IND submission, Hana plans to execute the clinical protocol and administer clinical trials for the ondansetron oral spray product.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Alprazolam. The Company plans to request a pre-IND meeting with the FDA with an anticipated goal of filing the IND during the first half of calendar year 2006. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the alprazolam oral spray product.

Propofol. We continue to support our partner, Manhattan Pharmaceuticals, who has filed an IND with the FDA. Manhattan Pharmaceuticals will oversee all clinical development and regulatory approval for this product.

Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals. In April 2005, the first designated compound was determined. NovaDel has commenced formulation of this designated compound.



The Company plans to hire additional employees in the laboratory to support our research and development efforts going forward; however, we do not believe that a significant number of new employees will be required in the next 12 months.

## RESULTS OF OPERATIONS

### THREE MONTHS ENDED OCTOBER 31, 2005 AND 2004

License fees and milestone fees earned from related parties for the three months ended October 31, 2005 were \$41,000, as compared to \$19,000 for the three months ended October 31, 2004. The \$22,000 increase is primarily due to the signing of new partnership agreements with Hana and Velcera late in the quarter ended October 31, 2004. As such, the quarter ended October 31, 2004 only included a partial quarter of license fees.

Consulting revenues from related parties for the three months ended October 31, 2005 were \$109,000 as compared to \$99,000 for the three months ended October 31, 2004. The \$10,000 increase is primarily due to increased revenue associated with the Company's arrangement with Velcera, partially offset by lower revenue from our arrangement with Manhattan.

Research and development expenses for the three months ended October 31, 2005 were \$897,000, as compared to \$660,000 for the three months ended October 31, 2004. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The increase in research and development expenses is primarily related to the following items:

- Approximate \$125,000 increase primarily related to product development costs for the Company's Zolpidem (Ambien®) product candidate
- Approximate \$126,000 increase related to higher lab supplies expense

Consulting, selling, general and administrative expenses for the three months ended October 31, 2005 were \$1,871,000 as compared to \$1,736,000 for the three months ended October 31, 2004. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The increase in consulting, selling, general and administrative costs is primarily related to the following items:

- Approximate \$138,000 charge related to severance costs for a former officer of the Company
- \$335,000 non-cash charge in the three months ended October 31, 2005 for stock-compensation expense
- Approximate \$117,000 decrease in outside consultant legal costs

The remaining increase, net of individually offsetting items of lesser significance, is primarily attributable to higher payroll and recruiting costs

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Primarily as a result of the factors described above, total costs and expenses for the three months ended October 31, 2005 were \$2,768,000 as compared to \$2,396,000 for the three months ended October 31, 2004.

Interest income for the three months ended October 31, 2005 was \$43,000 as compared to \$22,000 for the three months ended October 31, 2004 due to a general increase in interest rates.

The resulting net loss for the three months ended October 31, 2005 was \$2,575,000 as compared to \$2,256,000 for the three months ended October 31, 2004.

### **LIQUIDITY AND CAPITAL RESOURCES**

From its inception, the Company's principal sources of capital were consulting revenues, private placements and a public offering of its securities, as well as loans and capital contributions from the Company's principal stockholders. The Company has had a history of recurring losses, giving rise to an accumulated deficit at October 31, 2005 of \$36,966,000. At October 31, 2005, we had working capital of approximately \$4,551,000 as compared to working capital of \$6,781,000 at July 31, 2005, representing a net decrease in working capital of approximately \$2,230,000. As explained further below, such decrease is primarily attributable to a decrease in cash, short-term investments and accounts payable, and an increase in prepaid expenses. In May 2005, the Company successfully closed an offering of its common stock and warrants to purchase shares of its common stock ( Private Placement ). The Private Placement involved the sale of approximately 6,733,024 shares of common stock, and warrants to purchase 2,356,559 shares of common stock. The Company received proceeds, net of offering costs, of approximately \$6,309,000.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

Net cash used in operating activities was approximately \$3,101,000 for the three months ended October 31, 2005, as compared to net cash provided by operating activities of approximately \$77,000 for the three months ended October 31, 2004. Net cash used in and provided by operating activities for both the three months ended October 31, 2005 and 2004 were more significantly affected by the net loss of \$2,575,000 and \$2,256,000, respectively, partially offset by an increase in deferred revenue in the three months ended October 31, 2004 of \$2,095,000. This increase in deferred revenue was attributable to payments received by the Company from its licensees, which payments are being amortized over the remaining terms of the agreements with the licensees. The following other significant items also impacted net cash used in operating activities in the three months ended October 31, 2005:

\$560,000 decrease in accounts payable primarily due to the payment of invoices included in accounts payable at July 31, 2005 related to the manufacturing and process development of the Company's nitroglycerin product candidate.

\$264,000 increase in prepaid expenses and other current assets primarily attributable to the prepayment of a portion of the process validation batches for the Company's nitroglycerin product candidate.

\$290,000 non-cash charge to record stock-compensation expense.

In the three months ended October 31, 2005, \$1,063,000 was provided by investing activities, principally from the maturities of investments, net of purchases of investments. In the three months ended October 31, 2004, \$982,000 was used in investing activities which primarily related to the purchase of investments, net of maturities of investments, which amounts exceeded capital expenditures. Capital expenditures for the three months ended October 31, 2004 totaled approximately \$513,000 and consisted primarily of leasehold improvements for the Company's new laboratory facility and manufacturing equipment at INyX for the manufacture of the Company's product candidate.

Cash provided by financing activities was approximately \$18,000 in the three months ended October 31, 2005, as compared to \$574,000 in the three months ended October 31, 2004. The \$556,000 decrease is primarily due to the three months ended October 31, 2004 including \$636,000 related to the proceeds received from the shares of common stock issued to Hana Biosciences, Inc.

Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and short-term investments, and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving product sales and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to it from third-party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Although we expect to have sufficient cash to fund our operations through fiscal 2006, we would have to significantly reduce the pace of our ongoing development of our six priority product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our six priority product candidates, we estimate that we will need to raise additional capital during fiscal year 2006 in order to fully fund our development activities through July 31, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. If we are unable to raise additional capital in fiscal 2006, we will likely be forced to curtail our desired development activities, which will delay the development of our product candidates. There can be no assurance that such capital will be available to us on favorable terms or at all. Management of the Company believes that no later than the fiscal quarter ending October 31, 2006, it will be necessary for the Company to obtain additional financing and/or consummate a strategic alliance with a business partner. There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside the control of the Company. The Company may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

**CRITICAL ACCOUNTING POLICIES**

USE OF ESTIMATES - The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States. This requires the Company's management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

15

---

**REVENUE RECOGNITION** - Revenue is recognized as earned. Invoices, for client project costs, are created and presented at the end of each month, for that month. Accounts receivable reflect these invoices at the end of the month in which the invoice was created. Consulting revenues from contract clinical research are recognized as earned. The Company also receives milestone and upfront payments which are initially deferred and subsequently amortized into revenue over the contractual period.

**STOCK-BASED COMPENSATION** Effective August 1, 2005, the Company has adopted SFAS 123R, Share-Based Payment. SFAS 123R establishes standards for the accounting for transactions in which an entity exchanges its equity instruments, such as shares, options or other share-based awards, for goods or services and requires that the compensation cost relating to all share-based payment transactions be recognized in the financial statements, measured by the fair value of the equity instruments issued. Options or stock awards issued to non-employees and consultants are recorded at their fair value as determined in accordance with SFAS No. 123R and EITF No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees For Acquiring, or in Conjunction with Selling, Goods or Services, and recognized over the related vesting or service period. The fair value of options and similar instruments is determined using the Black-Scholes valuation model which employs weighted average assumptions for expected volatility of the Company's stock, expected term until exercise of the options, the risk free interest rate, and dividends, if any. We have elected the modified prospective transition method which requires that compensation costs be recorded, as earned, for all unvested stock options outstanding at July 31, 2005. For the three months ended October 31, 2005, the Company recorded share-based compensation of approximately \$350,000 or \$.01 per share. The Company will continue to incur share-based compensation charges in future periods.

As a result of cashless exercise provisions in its employee stock option agreements, the Company has used variable accounting treatment under the Financial Accounting Standards Board's Interpretation 44, for issue and outstanding stock options since January 2002. On October 20, 2004, the Board of Directors of the Company rescinded the Company's cashless exercise provision for all of the Company's outstanding option grants. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options of the Company, for which option exercise prices were modified from the original agreement.

#### **RESEARCH AND DEVELOPMENT EXPENSES**

Research and development expenses are expensed as incurred.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on its financial condition, results of operations, liquidity or capital resources.

#### **CONTRACTUAL OBLIGATIONS**

Our major outstanding contractual obligations relate to our operating leases, employment agreements, and license agreements with our strategic partners. Since July 31, 2005, there have been no material changes with respect to our contractual obligations as disclosed in the Notes to the Financial Statements in our annual report on Form 10-KSB for the year ended July 31, 2005.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Our holdings of financial instruments consist of certificates of deposit and U.S. Treasury securities. Our market risk exposure consists principally of exposure to changes in interest rates.

**ITEM 4. CONTROLS AND PROCEDURES.**

(a) Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 ( Exchange Act ) is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's ( SEC's ) rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of October 31, 2005. Based on this evaluation, the Company's Chief Executive Officer and its Chief Financial Officer concluded that as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

The Company's management, including its Chief Executive Officer and its Chief Financial Officer, does not expect that disclosure controls or internal controls over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

(b) Changes in Internal Controls

During the three months ended October 31, 2005, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

**RISK FACTORS**

The Risk Factors included in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005 have not materially changed other than as set forth below.

**WE ARE A PRE-COMMERCIALIZATION COMPANY, HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE.**

We are a pre-commercialization specialty pharmaceutical company. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition.

We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.



We had an accumulated deficit as of October 31, 2005 of approximately \$37.0 million. We incurred losses in each of our last nine fiscal years, including a net loss of approximately \$9.5 million for the fiscal year ended July 31, 2005, and a net loss of \$2.6 million for the three months ended October 31, 2005. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

**WE ARE DEPENDENT ON EXISTING MANAGEMENT.**

Our success is substantially dependent on the efforts and abilities of the principal members of our management team and our directors. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services would have a materially adverse effect on our business operations and prospects. Although our employment agreements with members of management generally provide for severance payments that are contingent upon the applicable officer's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

On September 6, 2005, the Board of Directors of the Company announced that they would not be renewing the employment contract of Dr. Shangold. Accordingly, Dr. Shangold will cease to be the President and Chief Executive Officer of the Company on December 22, 2005.

On September 2, 2005, the Board elected Robert G. Savage, a current Director and a highly experienced professional in the pharmaceutical industry, as non-executive Chairman of the Board. Mr. Savage will continue to serve as a member of the Audit Committee and the Corporate Governance and Nominating Committee of the Board. On October 19, 2005, the Board of Directors appointed William F. Hamilton as Chairman of the Corporate Governance and Nominating Committee. There was no arrangement or understanding between Mr. Savage and any other persons pursuant to which Mr. Savage was elected non-executive Chairman of the Board of Directors and there are no related party transactions between Mr. Savage and the Company. On November 22, 2005, the Company announced that board of directors member, and non-executive Chairman of the Board, Robert G. Savage has announced his intention not to stand for re-election to NovaDel's board at the company's 2006 annual meeting of shareholders. Mr. Savage has served as a director of the company since 2004.

On September 28, 2005, the Board announced its appointment of Dr. Jan H. Egberts as the Company's Chief Operating Officer, effective September 26, 2005, reporting to the Chairman of the Board. Dr. Egberts will assume the positions of President and Chief Executive Officer of the Company on December 23, 2005. There was no arrangement or understanding between Dr. Egberts and any other persons pursuant to which Dr. Egberts was elected Chief Operating Officer and there are no related party transactions between Dr. Egberts and the Company.

On December 15, 2005, the Company announced that board of directors member, Mark Rachesky has announced his intention not to stand for re-election to NovaDel's board at the company's 2006 annual meeting of shareholders. Mr. Rachesky has served as a director of the company since 2003.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including scientific, development and manufacturing staff.

**ADDITIONAL AUTHORIZED SHARES OF OUR COMMON STOCK AND PREFERRED STOCK AVAILABLE FOR ISSUANCE MAY ADVERSELY AFFECT THE MARKET.**

We are authorized to issue a total of 100,000,000 shares of common stock. As of December 1, 2005, there were 40,647,318 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of October 31, 2005, we had outstanding stock options and warrants to purchase approximately 28,059,000 shares of common stock, the exercise price of which range between \$0.46 per share to \$3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. Of the reserved shares, a total of 4,400,000 shares are currently reserved for issuance in connection with our 1992, 1997 and 1998 Stock Option Plans, respectively, of which options to purchase an aggregate of 500,000, 500,000 and 3,125,500, shares have been issued under the respective stock option plans. Another 4,050,000 shares are reserved for issuance

and available for the non-plan options granted pursuant to the terms of the employment agreements of various of our current and former officers. To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution. In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

See Risk Factors - Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders included in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board of Directors. We presently have no issued and outstanding shares of preferred stock and while we have no present plans to issue any shares of preferred stock, our Board of Directors has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

#### **ITEM 5. OTHER INFORMATION.**

On November 22, 2005, the Company announced that board of directors member, and non-executive Chairman of the Board, Robert G. Savage has announced his intention not to stand for re-election to NovaDel's board at the company's 2006 annual meeting of shareholders. Mr. Savage has served as a director of the Company since 2004.

On December 15, 2005, the Company announced that board of directors member, Mark Rachesky has announced his intention not to stand for re-election to NovaDel's board at the company's 2006 annual meeting of shareholders. Mr. Rachesky has served as a director of the company since 2003.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NovaDel Pharma Inc.**

Date: December 15, 2005                      By:                      /S/ GARY A. SHANGOLD  
Gary A. Shangold, M.D.  
President and Chief Executive Officer

Date: December 15, 2005                      By:                      /S/ MICHAEL E. SPICER  
Michael E. Spicer  
Chief Financial Officer

**ITEM 6. EXHIBITS.**

**INDEX TO EXHIBITS**

The following exhibits are included with this Quarterly Report. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
31.1	Certification Pursuant to Rule 13a-14(a)	Filed herewith
31.2	Certification Pursuant to Rule 13a-14(a)	Filed herewith
32	Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith



Exhibit 31.1

**CERTIFICATION**

Pursuant to Rule 13a-14(a)

I, Gary A. Shangold, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NovaDel Pharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [intentionally omitted]

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 15, 2005

By:

/S/ GARY A. SHANGOLD  
Gary A. Shangold, M.D.  
President and Chief Executive Officer

Exhibit 31.2

**CERTIFICATION**

Pursuant to Rule 13a-14(a)

I, Michael E. Spicer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NovaDel Pharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [intentionally omitted]

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and



Edgar Filing: NOVADEL PHARMA INC - Form 10-Q

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 15, 2005

By:

/S/ MICHAEL E. SPICER  
Michael E. Spicer  
Principal Financial Officer

Exhibit 32

**CERTIFICATIONS**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(18 U.S.C. 1350)

In connection with the Quarterly Report of NovaDel Pharma Inc., a Delaware corporation (the Company), on Form 10-Q for the period ended October 31, 2005, as filed with the Securities and Exchange Commission (the Report), Gary A. Shangold, M.D., President and Chief Executive Officer of the Company, and Michael E. Spicer, Principal Financial Officer of the Company, respectively, do each hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. ss. 1350), that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 15, 2005                      By:                      /s/ Gary A. Shangold  
Gary A. Shangold, M.D.  
President and Chief Executive Officer

Date: December 15, 2005                      By:                      /s/ Michael E. Spicer  
Michael E. Spicer  
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

