NOVADEL PHARMA INC
Form 10QSB
December 15, 2004

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

|X| QUARTERLY REPORT UNDER SECTION 13 or 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended October 31, 2004

| | TRANSITION REPORT UNDER SECTION 13 or 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to_____

Commission file number 001-32177

NOVADEL PHARMA INC.
(Exact name of small business issuer as specified in its charter)

Delaware	22-2407152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
25 Minneakoning Road Flemington, New Jersey	08822
(Address of Principal Executive Offices)	(Zip Code)

(908) 782-3431
(Issuer's telephone number)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 |X| No |_|

APPLICABLE ONLY TO CORPORATE ISSUERS:

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 33,491,437 shares of common stock outstanding as of December 2, 2004.

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SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This Current Report on Form 10-QSB includes "forward-looking statements", including statements regarding the Company's 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 or Plan 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," and "intend" and similar expressions to identify forward-looking statements. 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; 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, 2004, and other

reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

NOVADEL PHARMA INC.
CONDENSED BALANCE SHEETS
AS OF OCTOBER 31, 2004 AND JULY 31, 2004

	October 31, 2004 (Unaudited)
ASSETS	
Current Assets:	
Cash and cash equivalents	$ 1,835,000
Short-term investments	6,439,000
Accounts receivable - trade	65,000
Prepaid expenses and other current assets	281,000
Total Current Assets	8,620,000
Property and equipment, net	1,472,000
Long-term investments	1,548,000
Other assets	351,000
Other investment	500,000
TOTAL ASSETS	$12,491,000
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable-trade	$ 275,000
Accrued expenses and other current liabilities	827,000
Current portion of deferred revenue	162,000
Current portion of capitalized lease obligation	-
Total Current Liabilities	1,264,000
Non current portion of deferred revenue	2,795,000
Non current portion of capitalized lease obligation	-
Total Liabilities	4,059,000
COMMITMENTS AND CONTINGENCIES	

STOCKHOLDERS' EQUITY:	
Preferred stock, $.01 par value: Authorized 1,000,000 shares, none issued	
Common stock, $.001 par value: Authorized - 100,000,000 shares Issued and outstanding 33,491,437 shares at October 31, 2004 and 33,091,467 shares at July 31, 2004	33,000
Additional paid-in capital	35,602,000
Accumulated deficit	(27,197,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)
Total Stockholders' Equity	8,432,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 12,491,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended October 31,	
	2004	200 As Restated
LICENSE FEE	$19,000	
CONSULTING REVENUES	99,000	
TOTAL REVENUES	118,000	
RESEARCH AND DEVELOPMENT EXPENSES	660,000	2
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,736,000	7
TOTAL EXPENSES	2,396,000	1,0
LOSS FROM OPERATIONS	(2,278,000)	(1,0
INTEREST INCOME	22,000	
NET LOSS	$ (2,256,000)	$ (1,0
BASIC AND DILUTED LOSS PER SHARE	$(.07)	
SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	33,100,163	17,9

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
(Note 3)

	Common Stock			
	Shares	Amount	Additional Paid-in Capital	Accumula Defici
BALANCE, August 1, 2004	33,091,437	$33,000	$34,937,000	$(24,94
Impact of variable plan accounting	-	-	29,000	
Shares issued to Hana Biosciences Inc. per license agreement	400,000	-	636,000	
Net Loss	-	-	-	(2,25
BALANCE, October 31, 2004	33,491,437	$33,000	$35,602,000	$(27,19

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three M Oct
	2004
CASH FLOWS FROM OPERATING ACTIVITIES:	
Net loss	$ (2,256,000)
Adjustments to reconcile net loss to net cash used in operating activities:	
Impact of variable plan accounting	29,000
Depreciation and amortization	107,000
Changes in operating assets and liabilities:	
Accounts receivable	65,000
Prepaid expenses and other current assets	(26,000)
Other assets	-

Accounts payable - trade	34,000
Accrued expenses and other current liabilities	29,000
Deferred revenue	2,095,000
Net cash provided by (used in) operating activities	77,000
CASH FLOWS FROM INVESTING ACTIVITIES:	
Purchase of investments	(4,280,000)
Maturities of investments	3,811,000
Purchase of property and equipment	(513,000)
Net cash used in investing activities	(982,000)
CASH FLOWS FROM FINANCING ACTIVITIES:	
Proceeds from shares of common stock issued to Hana Biosciences	636,000
Payments on capital lease obligation	(62,000)
Net cash provided by financing activities	574,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(331,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,166,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$1,835,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:	
Equipment acquired under capitalized lease obligation	$ -
Investment in Hana Biosciences common stock received in connection with license agreement	$500,000

See accompanying notes to condensed financial statements.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

THE COMPANY - 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 a lingual spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. 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 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 offers 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's strategy is to concentrate its product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of the Company's proprietary, novel drug delivery technology will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance.

The Company has identified six tier-one 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 tier-one priority programs. These initiatives include, among other products, clemastine, loratadine and estradiol and progesterone lingual sprays.

To date, 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 lingual spray, and (iv) Hana Biosciences Inc. ("Hana"), for the marketing rights in the United States and Canada for the Company's ondansetron lingual

spray. Recently, the Company entered into an agreement with INyX USA, Ltd. for the manufacture and supply of the Company's nitroglycerin lingual spray (see Note 7). The Company has not entered into any material development arrangements with any pharmaceutical companies. The Company believes that it will require additional financing and/or additional alliances with development partners to undertake and maintain its business plan.

BASIS OF PRESENTATION - The balance sheet at July 31, 2004, the end of the preceding fiscal year, has been derived from the audited balance sheet contained in the previously filed Annual Report on Form 10-KSB of the Company for the fiscal year ended July 31, 2004, 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. The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make certain estimates and assumptions that affect reported earnings, 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 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, 2004.

The Company has reported a net loss of $2,256,000 for the three months ended October 31, 2004 and a net loss of $1,030,000 for the three months ended October 31, 2003, as restated (see Note 3). Management believes that the Company will continue to incur net losses through at least October 31, 2005. Management believes that the Company's capital resources will be adequate to fund operations through at least October 31, 2005. As of October 31, 2004, the Company had working capital of $7,356,000, cash and cash equivalents of $1,835,000 and short-term investments of $6,439,000. Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and marketable investments. 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 the Company's equity or debt securities or bridge loans to the Company from third party lenders.

Management of the Company believes that no later than the fiscal quarter ending January 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.

NOTE 2 - LOSS PER COMMON SHARE

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, 2004 and 2003, there were 20,119,000 and 15,507,000 shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per share computation.

NOTE 3 - RESTATEMENT OF FINANCIAL STATEMENTS

In connection with the preparation of the Company's Annual Report on Form 10-KSB of the Company for the fiscal year ended July 31, 2004, the Company's independent registered public accounting firm brought to the attention of the Company that certain of the Company's issued and outstanding stock options should have been subject to variable plan accounting treatment under applicable accounting standards and, accordingly, previously unrecognized compensation expenses should have been 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). After reviewing the matter with its current and former independent registered public accounting firms, the Company identified certain adjustments that necessitated the restatement of its financial statements for the first three quarters of fiscal 2004, the interim periods of fiscal 2003 and 2002, and for the fiscal years 2003 and 2002.

These adjustments reflect variable plan accounting treatment of the affected stock options for the relevant periods, resulting from cashless exercise provisions applicable to options held by employees and directors. Under variable plan option accounting, compensation expense is increased or decreased as a result of changes in the market price of the Company's common stock. The restatement adjustment for the three months ended October 31, 2003 resulted in credits to Research & Development and Consulting, Selling, General and Administrative Expenses of $24,000 and $671,000, respectively. For the three months ended October 31, 2003, net loss decreased by $695,000 as a result of the variable plan accounting treatment adjustment.

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. Thus, the Company expects that variable accounting will no longer be required after the end of the Company's fiscal quarter ended October 31, 2004.

NOTE 4 - INVESTMENTS

Investments include short-term investments, long-term investments and an investment in common stock received from a licensee (See Note 6). Short-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit and US treasury securities with original maturities greater than three months and less than one year. Long-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit, and US treasury securities with maturities greater than one year. Unregistered, nonmarketable common stock received from the licensee is carried at cost.

NOTE 5 - STOCK OPTIONS AND WARRANTS

The Company uses the intrinsic value method of accounting for stock options pursuant to the provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options. Because the exercise price of the Company's stock options equals or exceeds the market price of the underlying stock on the date of grant, no compensation expense is initially recognized under APB 25. Compensation expense and credits were recorded as a result of variable plan accounting for options with cashless exercise provisions. Had compensation costs been determined using the Black-Scholes option pricing model in accordance with the fair value method prescribed by "Accounting for Stock-Based Compensation" (SFAS 123) for all options issued to SFAS No. 123, employees and amortized over the vesting period, the Company's net loss applicable to common shares and net loss per common share (basic and diluted) would have been increased to the pro forma amounts indicated below.

	THREE MONTHS ENDED OCTOBER 31,	
	2004	
Net loss, as reported	$ (2,256,000)	$ (1
Compensation expense (credit) 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)	$(1
Loss per share:		
Basic and diluted, as reported	$(.07)	
Basic and diluted, pro forma	$(.07)	

The fair market value of options granted during the three-month period ended October 31, 2004 and 2003 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 61% for the three months ended October 31, 2004; 55-67% for the three months ended October 31, 2003; and a weighted-average expected life of the options of five to 10 years for the three months ended October 31, 2004 and 2003.

During the fiscal quarter ended October 31, 2004, the Company granted 60,000 options to an employee under the 1998 Stock Option Plan. These options vest equally over three years and expire in 10 years. The exercise price of the options granted during this fiscal quarter is $1.82. During such quarter, the Company also issued 10,000 options to a former board member. These options have an exercise price of $1.72 and vested immediately.

NOTE 6 - RELATED PARTY TRANSACTIONS - LICENSE AND DEVELOPMENT AGREEMENTS

In April 2003, the Company entered into a license and development agreement with Manhattan for the worldwide, exclusive rights to the Company's proprietary lingual 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 fiscal year ended July 31, 2004, the Company invoiced Manhattan approximately $400,000 for 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. During the three months ended October 31,

2004, the Company invoiced Manhattan approximately $65,000 for reimbursable expenses.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The agreement is for the exclusive rights to the Company's propriety lingual spray technology for animals. In September 2004, the Company received $1,500,000 from Velcera in connection with the agreement. The upfront payment has been included in deferred revenue and is being recognized in income over the 20-year term of the agreement. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement.

In October 2004, the Company entered into a license and development agreement pursuant to which, the Company granted to Hana an exclusive license to develop and market the Company's lingual spray version of ondansetron 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 of $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 period of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement.

Lindsay A. Rosenwald, M.D., a significant stockholder of the Company, may be deemed to be an affiliate of the Company, Manhattan, Velcera and Hana. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to the Company's agreements with the parties to such agreements from time to time.

NOTE 7 - SUBSEQUENT EVENTS

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 beginning November 18, 2004, INyX will be the exclusive provider of the nitroglycerin lingual spray to the Company worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. 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. The targeted date for INyX to commence production is presently mid-2005.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

Since the Company's inception, substantially all of its revenues have been derived from consulting activities and license fees, primarily in connection with product development for various pharmaceutical companies. The Company has had a history of recurring losses from operations, giving rise to an accumulated deficit at October 31, 2004, of approximately $27,197,000. 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 enter into additional license agreements with drug companies who will market and distribute the final products.

Over the next fiscal year, the Company intends to continue to stay focused on its six tier-one priority products: nitroglycerin, sumatriptan, ondansetron, zolpidem, alprazolam and propofol. The Company currently has cash and marketable investment balances of approximately $9,822,000, which the Company believes are sufficient to maintain operating costs until at least October 31, 2005. The Company continues to seek collaborative arrangements with pharmaceutical companies for joint development of delivery systems and the successful marketing of these delivery systems. In view of the Company's limited resources, its anticipated expenses (resulting in significant operating losses) and the competitive environment in which the Company operates, the Company anticipates that it will need to pursue a financing by the end of the fiscal quarter ending January 31, 2006. See "Liquidity and Capital Resources" below.

RESULTS OF OPERATIONS

THE THREE MONTHS ENDED OCTOBER 2004 (THE "2005 PERIOD") COMPARED TO OCTOBER 2003 (THE "2004 PERIOD")

Consulting and license fee revenues for the 2005 Period increased approximately $116,000 to $118,000 from $2,000 for the 2004 Period. This revenue increase for the 2005 Period was attributable to an increase in consulting assignments and revenue attributable to the Company's arrangements with Manhattan in addition to amortization of deferred revenue from license fees received.

Research and development expenses increased approximately $391,000 to $660,000 from $269,000 for the 2005 Period. The increase in research and development expenses is primarily related to outsourced manufacturing fees, purchases of additional laboratory and manufacturing supplies and increased Pharmacokinetic study activities for the Company's tier-one products.

Consulting, selling, general and administrative expenses increased approximately $967,000 to $1,736,000 from $769,000 for the 2005 Period. The increase in consulting, selling, general and administrative expenses is related to increased payroll, recruiting and relocation expenses as a result of hiring additional employees, higher accounting and legal fees, increased travel and trade show attendance, increased rent expense due to the leasing and occupying of additional space for the Company's operations and a $671,000 decrease in compensation expense related to variable accounting adjustments to certain of

the Company's outstanding stock options in the 2004 Period. As a result of the factors described above, total costs and expenses for the 2005 Period increased approximately $1,358,000 to approximately $2,396,000 compared to the 2004 Period.

Interest income increased approximately $16,000 to $22,000 for the 2005 Period from $6,000 for the 2004 Period as a result of the $12.8 million received from the January 2004 private placement of the Company's common stock, the remaining portion of which is invested in liquid securities.

The resulting net loss for the 2005 Period was $2,256,000 compared to a net loss of $1,030,000 for the 2004 Period.

LIQUIDITY AND CAPITAL RESOURCES

Net cash provided by operating activities approximated $77,000 for the 2005 Period compared to net cash used in operating activities of approximately $1,462,000 for the 2004 Period. Net cash used in operating activities for both the 2005 and 2004 periods was primarily attributable to the net loss of $2,256,000 and $1,030,000, respectively, offset by an increase in deferred revenue for the 2005 Period of $2,095,000. For the 2005 Period, $981,000 was used for investing activities, principally for capital expenditures and purchases of liquid investments, net of maturities, compared to $308,000 for the 2004 Period. For the 2005 Period, financing activities provided approximately $574,000, which consisted of cash received for shares issued to Hana offset by payments on a capital lease.

The Company has reported a net loss of $2,256,000 for the three months ended October 31, 2004 and a net loss of $1,030,000 for the three months ended October 31, 2003, as restated (see Note 3). Management believes that the Company will continue to incur net losses through at least October 31, 2005. Management believes that the Company's capital resources will be adequate to fund operations through at least October 31, 2005. As of October 31, 2004, the Company had working capital of $7,356,000, cash and cash equivalents of $1,835,000 and short-term investments of $6,439,000. Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and marketable investments. 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.

Management of the Company believes that by the end of the fiscal quarter ending January 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, if at all.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for the first quarter 2005 Period and the 2004 Period were $660,000 and $269,000, respectively. The Company's research and development costs are expensed as incurred. These include all internal costs, external costs related to services contracted by the Company and research services conducted for others. 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. These cost categories typically include the expenses discussed below. The increase in research and development expenses is

primarily related to outsourced manufacturing fees, purchases of additional laboratory and manufacturing supplies and increased Pharmacokinetic study activities for the Company's tier-one products.

RESEARCH AND PRE-CLINICAL OPERATIONS

Research and pre-clinical operations reflect activities associated with research prior to the initiation of any potential human clinical trials. These activities predominantly represent projects associated with the formulation development of lingual sprays which may include animal safety studies and validation testing.

DIRECT EXPENSES - CLINICAL TRIALS

Direct expenses of clinical trials include patient enrollment costs, external site costs, expense of clinical drug supply and external costs such as contract research consultant fees and expenses.

MANUFACTURING DEVELOPMENT

Manufacturing Development primarily reflects costs incurred to prepare current good manufacturing procedures (cGMP) manufacturing capabilities in order to provide clinical scale drug supply. These costs primarily reflect activities with external contract manufacturing resources. Included in manufacturing development are personnel costs, depreciation, expenses associated with technology transfer, process development and validation, quality control and assurance activities, and analytical services.

UNALLOCATED DEVELOPMENT - CLINICAL AND REGULATORY OPERATIONS

Clinical and regulatory operations reflect the preparation, implementation and management of the Company's clinical trial activities in accordance with current good clinical practice (cGCP). Included in unallocated clinical development and regulatory operations are costs associated with personnel, supplies, facilities, fees to consultants, other related costs for clinical trial implementation and management, clinical quality control, regulatory compliance activities, data management and biostatistics.

The following summarizes the Company's research and development expenses by the foregoing categories for the fiscal quarters ended October 31, 2004 and 2003:

	QUARTER ENDED October 31,	
	2004	2003
RESEARCH AND DEVELOPMENT EXPENSES:		
Research and pre-clinical operations	$ 15,000	$ 16,000
Direct clinical trial expenses	132,000	66,000
Manufacturing development	30,000	-
Unallocated development	483,000	187,000
RESEARCH AND DEVELOPMENT EXPENSES	$660,000	$269,000

OFF BALANCE SHEET ARRANGEMENTS

The Company has no off balance sheet arrangements within the meaning of SEC rules.

INFLATION

The Company does not believe that inflation has had a material effect on its results of operations during the past three fiscal years. There can be no assurance that the Company's business will not be affected by inflation in the future.

RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimated. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretations and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of the Company's drug product candidates are available for commercial sale. All of the Company's potential products are in regulatory review, clinical development or pre-clinical development. The status of each of the Company's six tier-one priority products is discussed in "General," above. Successful completion of development of the Company's six tier-one priority programs are contingent on numerous risks, uncertainties, and other factors, which are described in the section entitled "Risk Factors" in Item 5 of Part II of the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2004. These factors include:

- Completion of pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval

- Receipt of necessary regulatory approvals

- Obtaining adequate supplies of sufficient raw materials on commercially reasonable terms

- Obtaining capital necessary to fund the Company's operations, including the Company's research and development efforts, manufacturing requirements and clinical trials

- Performance of third-party collaborators on whom the Company relies heavily for the commercialization and manufacture of drug product

- Obtaining manufacturing, sales and marketing capabilities for which the Company presently has limited resources

As a result of the amount and nature of these factors, many of which are outside the Company's control, the success, timing of completion and ultimate cost of development of any of the Company's product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- Slow patient enrollment
- Long treatment time required to demonstrate effectiveness
- Lack of sufficient clinical supplies and material
- Adverse medical events or side effects in treated patients
- Lack of effectiveness of the product candidate being tested
- Lack of sufficient funds

If the Company does not successfully complete clinical trials, the Company will not receive regulatory approval to market its six tier-one priority products. If the Company does not obtain and maintain regulatory approval for its products, the Company will not generate any revenues from the sale of its products and the Company's value and its financial condition and results of operations will be substantially harmed.

The Company is engaged in research and development activities which often provide services and transfer rights under complex licensing agreements. The arrangements may include payment terms that include receipt of up-front fees and milestone payments. The Company has entered into such arrangements which contain multiple elements including up-front fees, milestone payments, royalty fees and equity issuances, among others. Different methods of accounting for revenue and expense recognition may be appropriate under each of these arrangements. It is currently expected that upfront and milestone payments will be recognized over the life of the relevant agreements.

The Company presently has four major agreements with each of Manhattan, Par, Velcera and Hana. The Company is entitled to certain milestone payments and double-digit royalties, generally on either net sales or gross revenues. It is speculative as to when any such payments or royalties will be earned or paid, if at all. On November 18, 2004, the Company entered into a Manufacturing and Supply Agreement with INyX, whereby INyX will be the exclusive provider of the nitroglycerin lingual spray to the Company worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. See Note 7 to the Financial Statements.

ITEM 3. 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 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.

The Company's Chief Executive Officer and its Interim Principal Financial Officer have evaluated 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 the end of the period covered by this

Quarterly Report on Form 10-QSB. Based on this evaluation, the Company's Chief Executive Officer and its Interim Principal Financial Officer concluded that as of the end of the period covered by this report, except as set forth below, 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.

In connection with its audit of the Company's financial statements for the fiscal year ended July 31, 2004, J.H. Cohn LLP, the Company's independent registered public accounting firm ("J.H. Cohn"), brought to the attention of the Company that certain issued and outstanding options that permit "cashless exercise" should be subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expense needed to be recognized as compensation expense 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). See Note 3 to Notes to Financial Statements.

J.H. Cohn also advised the Audit Committee and management of certain material weaknesses, including the failure to record and retain comprehensive option grants issued by the Company, inability to prepare financial statements and footnotes in accordance with U.S. generally accepted accounting principles and SEC rules, a lack of an appropriate system of policies and procedures for the

internal review of financial reports, including inadequate staffing, training and expertise and improper accounting procedures for grants with "cashless exercise" provisions per Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions Involving Stock Compensation - an interpretation of APB Opinion No. 25". J.H. Cohn indicated that they considered these deficiencies to be material weaknesses as that term is defined under standards established by the Public Company Accounting Oversight Board (United States). These material weaknesses also included the following: a lack of effective documentation for stock options and other compensatory equity grants; the absence of a procedure to obtain from officers and directors information required to be disclosed about such persons; the absence or ineffectiveness of a rule compliance checking procedure for SEC filings; and lack of effective record keeping and compliance assistance for reports required under Section 16(a) of the Exchange Act.

In light of the need for a restatement and the material weaknesses in the Company's internal controls, commencing in the first quarter of the Company's 2005 fiscal year, the Company began to undertake a review of the Company's disclosure, financial information and internal controls and procedures. This review will include increased diligence by the Company's management and directors, as well as the use of additional outside resources. The Company is committed to addressing its control environment and reporting procedures.

The Company believes that the hiring of a new Chief Financial Officer is important to its efforts to improve its internal controls, particularly with respect to its need to comply with Section 404 of the Sarbanes-Oxley Act of 2002. The Company has completed its search for a new Chief Financial Officer and has identified a potential candidate for the position. Although there can be no assurance, the Company anticipates employing the new Chief Financial Officer by

the end of the calendar year.

To address the weaknesses identified in the Company's internal controls and disclosure practices, the Company has drafted written disclosure controls and procedures applicable to periodic reports and certain public communications. By the end of the calendar year, the Company will have a Disclosure Committee, which will be chaired by the Company's Vice President and General Counsel and comprised of other executives. The Disclosure Committee will establish, maintain, monitor and evaluate the Company's written disclosure controls and procedures and coordinate the preparation of the Company's periodic reports and certain other of its public communications pursuant to formal written disclosure controls and procedures.

On October 20, 2004, the Board of Directors of the Company rescinded the cashless exercise provision for all of the Company's outstanding option grants. Thus, the Company expects that variable accounting will no longer be required after the Company's fiscal quarter ended October 31, 2004. To address weakness in recordkeeping related to issued option grants, the Company is planning to evaluate, test and install software to assist in the reconciliation of options and warrants issued by the Company.

The Company's management, including its Chief Executive Officer and its Interim Principal 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Not applicable.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable.

ITEM 6. EXHIBITS.

Exhibit No.	Description
10.33	*License and Development Agreement, dated as of October 27, 2004, by and between the Company and Hana Biosciences, Inc.
10.34	Manufacturing and Supply Agreement, dated as of November 18, 2004, by and between the Company and INyX USA, Ltd.
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Chief Financial Officer
32.1	Certification under 18 U.S.C. 1350
32.2	Certification under 18 U.S.C. 1350

*Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the SEC.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NOVADEL PHARMA INC.

Dated: December 15, 2004

By: /s/ Gary A. Shangold, M.D.

Gary A. Shangold, M.D.
President & Chief Executive Officer

Dated: December 15, 2004

By: /s/ Howard D. Kance

Howard D. Kance
Interim Principal Financial Officer