NOVADEL PHARMA INC
Form 10QSB
June 14, 2005
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 April 30, 2005

____ 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: 40,567,318 shares of common stock outstanding as of June 14, 2005.

Index

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 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 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, 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, 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 APRIL 30, 2005 (Unaudited) AND JULY 31, 2004

	April 30, 2005 (Unaudited)	July 31, 2004 (Note 1)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,272,000	$ 2,166,000
Short-term investments	2,742,000	6,211,000
Accounts receivable from related parties	229,000	130,000
Inventories	433,000	
Prepaid expenses and other current assets	223,000	255,000
Total Current Assets	4,899,000	8,762,000
Property and equipment, net	2,887,000	1,066,000
Long-term investments	99,000	1,307,000
Other assets	351,000	351,000
Other investment, at cost	500,000	
TOTAL ASSETS	$ 8,736,000	$ 11,486,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable - trade	$ 1,105,000	$ 241,000
Accrued expenses and other current liabilities	1,127,000	798,000
Current portion of deferred revenue	162,000	19,000
Current portion of capitalized lease obligation		28,000
Total Current Liabilities	2,394,000	1,086,000
Non current portion of deferred revenue	2,714,000	343,000
Non current portion of capitalized lease obligation		34,000
Total Liabilities	5,108,000	1,463,000
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		
	34,000	33,000

Issued and outstanding 33,834,294 shares at April 30, 2005 and 33,091,437 shares at July 31, 2004		
Additional paid-in capital	35,989,000	34,937,000
Accumulated deficit	(32,389,000)	(24,941,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders Equity	3,628,000	10,023,000
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 8,736,000	$ 11,486,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended April 30,		Nine Months Ended April 30,	
	2005	2004	2005	2004
		As restated (Note 3)		As restated (Note 3)
License Fees and Milestones Payments Earned from Related Parties	$ 91,000	$ 5,000	$ 151,000	8,000
Consulting Revenues from Related Parties	11,000	11,000	193,000	31,000
Total Revenues	102,000	16,000	344,000	39,000
Research And Development Expenses	851,000	581,000	2,270,000	1,236,000
Consulting, Selling, General And Administrative Expenses	1,907,000	1,025,000	5,812,000	2,987,000
Total Expenses	2,758,000	1,606,000	8,082,000	4,223,000
Loss From Operations	(2,656,000)	(1,590,000)	(7,738,000)	(4,184,000)
Interest Income	14,000	59,000	49,000	70,000
Loss Before Income Tax Benefit	(2,642,000)	(1,531,000)	(7,689,000)	(4,114,000)
Income Tax Benefit			241,000	214,000
Net Loss	$ (2,642,000)	$ (1,531,000)	$ (7,448,000)	$ (3,900,000)
Basic And Diluted Loss Per Share	$ (0.08)	$ (0.05)	$ (0.22)	$ (0.16)
Shares Used In Computation Of Basic And Diluted Loss Per Share	33,834,294	32,866,531	33,506,717	24,635,900

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	Accumulated Deficit	Treasury Stock	Total Stockholders Equity
BALANCE, August 1, 2004	33,091,437	$ 33,000	$ 34,937,000	$ (24,941,000)	$ (6,000)	$ 10,023,000
Impact of variable plan accounting			(101,000)			(101,000)
Stock issued to Hana Biosciences Inc. per license agreement	400,000		636,000			636,000
Stock issued for warrants exercised	142,857		200,000			200,000
Warrants issued for services			11,000			11,000
Stock issued to consultants for services	200,000	1,000	306,000			307,000
Net Loss				(7,448,000)		(7,448,000)
BALANCE, April 30, 2005	33,834,294	$ 34,000	$ 35,989,000	$ (32,389,000)	$ (6,000)	$ 3,628,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended April 30,	
	2005	2004 As Restated (Note 3)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,448,000)	$ (3,900,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	307,000	
Warrants issued for services	11,000	
Impact of variable plan accounting	(101,000)	(969,000)
Depreciation and amortization	282,000	162,000
Changes in operating assets and liabilities:		
Accounts receivable from related parties	(99,000)	(79,000)
Inventories	(433,000)	
Prepaid expenses and other current assets	32,000	(87,000)
Other assets		3,000
Accounts payable trade	864,000	12,000
Accrued expenses and other current liabilities	329,000	269,000
Deferred revenue	2,014,000	367,000
Net cash used in operating activities	(4,242,000)	(4,222,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of investments	(4,280,000)	
Sales of investments	1,096,000	
Maturities of investments	7,861,000	
Purchases of property and equipment	(2,103,000)	(380,000)
Net cash provided by (used in) investing activities	2,574,000	(380,000)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds received from issuance of common stock through a private placement offering		12,785,000
Proceeds from shares of common stock issued to Hana Biosciences	636,000	
Proceeds from options exercised		200,000
Proceeds from warrants exercised	200,000	
Payments on capitalized lease obligation	(62,000)	(18,000)
Net cash provided by financing activities	774,000	12,967,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(894,000)	8,365,000
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,166,000	3,086,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,272,000	$ 11,451,000

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Equipment acquired under capitalized lease obligation	$	$ 87,000
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. Currently, the Company has five patents which have been issued in the U.S. and five 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 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/or 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.

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.

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 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 Company had total fixed assets of $543,000 and inventories of $433,000 at the facilities of INyX as of April 30, 2005. Such assets are the property of the Company and cannot be used by INyX for any other business. In the event that the Company s contract with INyX is terminated for any reason, such assets are to be returned to the Company.

The Company has not entered into any other 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 Company s Annual Report on Form 10-KSB 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 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, 2004.

The Company has reported a net loss of $7,448,000 for the nine months ended April 30, 2005 and a net loss of $3,900,000 for the nine months ended April 30, 2004, as restated (see Note 3). Management believes that the Company will continue to incur net losses through at least April 30, 2006. As of April 30, 2005, the Company had working capital of $2,505,000, cash and cash equivalents of $1,272,000 and short-term investments of $2,742,000. Until and unless the Company s operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and short-term 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.

On May 26, 2005, the Company closed a private placement (the Offering) of 6,733,024 shares of its common stock at a price of $1.05 per share, and Class D warrants to purchase a total of 2,356,559 shares of common stock, with an initial exercise price equal to $1.30 per share, subject to adjustment. The Company received net proceeds of approximately $6,300,000 from the Offering. See Note 8.

Management of the Company believes that no later than the fiscal quarter ending April 30, 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.

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.

Inventory at April 30, 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). The scale-up and commercial production of pre-launch inventories involves the risk that product candidates may not be approved for marketing by the governmental agencies on a timely basis, or ever. The risk notwithstanding, the Company plans to continue to scale-up and build pre-launch inventories of this product candidate that has not yet received final government approval. On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol). See Note 8.

The Company records pre-launch inventory once the product candidate has attained either a stage in the development process of having been subject to a Phase III clinical trial or its equivalent and has a well-characterized manufacturing process. In addition, the Company must have an internal sales forecast that includes an assessment that sales will equal or exceed the manufacturing costs plus the expected costs to distribute the product.

Finally, product stability data must exist so that the Company can assert that capitalized inventory is anticipated to be sold, based on the sales projections noted above, prior to anticipated expiration of a product shelf-life.

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 $433,000 recorded as pre-launch inventory at April 30, 2005, this amount would be considered by the Company to be material to its operating results for the three and nine months ended April 30, 2005, and is likely to be considered material if such a write-off is required in a subsequent period.

Reclassification Certain prior year amounts have been reclassified to conform to the current year s presentation.

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 April 30, 2005 and 2004, there were 24,109,671 and 20,185,589 common shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per share computation. In conjunction with the Offering consummated on May 26, 2005, the Company issued additional warrants for the purchase of 2,693,210 common shares. See Note 8.

Note 3 - Restatement of Financial Statements

In connection with the preparation of the Company s Annual Report on Form 10-KSB for the fiscal year ended July 31, 2004, the Company s independent registered public accounting firm 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 . 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 and nine months ended April 30, 2004 resulted in credits to Research and Development Expenses of $6,000 and $29,000, respectively. In addition, the restatement adjustment for the three and nine months ended April 30, 2004 resulted in credits to Consulting, Selling, General and Administrative Expenses of $193,000 and $940,000, respectively. For the three and nine months ended April 30, 2004, net loss decreased by $199,000 and $969,000, respectively, 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. As a result, variable accounting will no longer be required to be applied to all option grants. However, variable accounting may still be required for certain option grants (see Note 5).

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 and classified as other investment.

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 or terms that have been modified. Had compensation costs been determined using the Black-Scholes option pricing model in accordance with the fair value method prescribed by SFAS No. 123 Accounting for Stock-Based Compensation (SFAS123) for all options issued to 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.

As noted above, 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 on October 20, 2004. Variable plan accounting is still required for approximately 340,000 outstanding options of the Company, for which option exercise prices were modified from the original agreements. These option agreements will continue to be accounted for under variable plan accounting until such time as they lapse or are exercised.

	Three Months Ended April 30,	
	2005	2004
Net loss, as reported	$ (2,642,000)	$ (1,531,000)
Compensation credit resulting from variable plan accounting	(96,000)	(199,000)
Total stock-based employee compensation expense using the fair-value based method for all awards	(217,000)	(52,000)
Pro forma net loss	$ (2,955,000)	$ (1,782,000)
Loss per share:		
Basic and diluted, as reported	$ (0.08)	$(0.05)
Basic and diluted, pro forma	$ (0.09)	$(0.05)

	Nine Months Ended April 30,	
	2005	2004
Net loss, as reported	$ (7,448,000)	$ (3,900,000)
Compensation credit resulting from variable plan accounting	(101,000)	(969,000)
Total stock-based employee compensation expense using the fair-value based method for all awards	(585,000)	(108,000)
Pro forma net loss	$ (8,134,000)	$ (4,977,000)
Loss per share:		
Basic and diluted, as reported	$(0.22)	$(0.16)
Basic and diluted, pro forma	$(0.24)	$(0.20)

The fair market value of options granted during the nine month periods ended April 30, 2005 and 2004 was 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 approximately 4.0%; dividend yield of 0.0%; volatility factors of 64% and 67% for the three and nine months ended April 30, 2005, respectively, and 54% and 57% for the three and nine months ended April 30, 2004, respectively; and a weighted-average expected life of the options of five to ten years for the nine months ended April 30, 2005 and 2004.

As a result of the amendments to SFAS 123, the Company will be required to expense the fair value of all options granted to employees over the vesting period beginning with the first quarter of fiscal 2007.

During the fiscal quarter ended April 30, 2005, the Company granted 60,000 options to employees under the 1998 Stock Option Plan. These options vest equally over three years and expire in five and ten years. The exercise prices of options granted during this fiscal quarter ranged from $1.37 to $1.41 per share.

On March 10, 2005 the Company appointed Thomas E. Bonney to its Board of Directors and chairman of the Audit Committee. Concurrent with his appointment, Mr. Bonney was granted 100,000 non-plan options to purchase common stock of the Company. Such options vest equally over three years, expire in five years and have an exercise price equal to $1.38 per share.

At the Annual Meeting of Stockholders held on February 28, 2005, all of the directors of the Company were re-elected to the Board for another term of one year. As a result, all five outside directors were each granted 50,000 non-plan options to purchase common stock of the Company, for a total of 250,000 options. Such options vest equally over three years, expire in five years and have an exercise price equal to $1.41 per share.

During the fiscal quarter ended January 31, 2005, the Company granted 750,000 options to employees 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 $1.53 per share. During such quarter, the Company recorded a charge to operations of $11,000 for 15,000 warrants issued to outside consultants, which expire in three years and which have an exercise price equal to $1.57 per share. In addition, the Company granted 200,000 fully vested restricted common shares to another consultant, which were valued at $307,000 using the market price on the date of grant. Such amount was recorded as a charge to operations.

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 these options was $1.82 per share. During such quarter, the Company also issued 10,000 options to a former board member. These options have an exercise price of $1.72 per share 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 and nine months ended April 30, 2005, the Company invoiced Manhattan approximately $0 and $119,000, respectively, 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 proprietary 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. During the three and nine months ended April 30, 2005, the Company invoiced Velcera approximately $11,000 and $74,000, respectively, for reimbursable expenses. Additionally, during the three months ended April 30, 2005, the Company invoiced Velcera $50,000 for a contractual milestone that was reached during the quarter.

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 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 period of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the three months ended April 30, 2005, the Company invoiced Hana approximately $84,000 for pass-through expenses incurred by the Company on behalf of Hana.

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 - Sale of Net Operating Loss Carryforwards

The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The Company recorded an income tax benefit of $241,000 and $214,000 for the nine months ended April 30, 2005 and 2004, respectively, from the sale of its New Jersey net operating loss carryforwards. If still available under New Jersey law, the Company may attempt to sell its remaining net operating loss carryforwards. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner.

Note 8 - Subsequent Events

Private placement - On May 26, 2005, the Company closed a private placement of 6,733,024 shares of common stock and Class D warrants to purchase a total of 2,356,559 shares of common stock, with an initial exercise price equal to $1.30 per share of common stock, subject to adjustment. The Company received net proceeds of approximately $6,300,000 from the Offering. The financing was led by ProQuest Investments and included the Caisse de dépôt et placement du Québec and others.

In connection with the Offering, the Company paid a cash commission equal to 7% of the gross proceeds from the Offering to Paramount BioCapital, Inc. (Paramount BioCapital), who acted as its placement agent, and issued to Paramount BioCapital a warrant to purchase 336,651 shares of common stock (the Placement Warrant). The Placement Warrant is exercisable at an initial exercise price equal to $1.30 per share (subject to adjustment). Paramount BioCapital is also entitled to an expense allowance of up to $50,000 to reimburse it for its out of pocket expenses incurred in connection with the Offering. The Company agreed to indemnify Paramount BioCapital against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the Offering. Paramount BioCapital and its affiliates are beneficial owners of a significant amount of shares of common stock and securities exercisable for shares of common stock and, accordingly, Paramount BioCapital may be deemed to be an affiliate of the Company.

Approvable letter received from the FDA On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol), indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The Company believes that the FDA will 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. NitroMist is a pending trademark of Par Pharmaceutical Companies, Inc.

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 April 30, 2005 of approximately $32,389,000. 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. As of April 30, 2005, the Company had cash and short and long-term marketable investment balances of approximately $4,113,000. Together with the net proceeds of approximately $6,300,000 from the May 2005 Private Placement described in Note 8, the Company believes such funds are sufficient to maintain operating costs until the quarter ended April 30, 2006. 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 additional financing by no later than the fiscal quarter ending April 30, 2006. See Liquidity and Capital Resources below.

NEW ACCOUNTING PRONOUNCEMENT

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment (SFAS 123R), which replaces SFAS No. 123, Accounting for Stock-Based Compensation, (SFAS 123) and supercedes APB Opinion No. 25, Accounting for Stock Issued to Employees. On April 14, 2005, the Securities and Exchange Commission (the SEC) adopted a rule amendment that delayed the compliance dates for SFAS 123R such that the Company is now allowed and plans to adopt the new standard on August 1, 2006. 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. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R and expects that the adoption of SFAS 123R will have a material impact on the Company s historical consolidated results of operations and earnings (loss) per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

RESULTS OF OPERATIONS

THE NINE MONTHS ENDED APRIL 30, 2005 (THE 2005 PERIOD) COMPARED TO THE NINE MONTHS ENDED APRIL 30, 2004 (THE 2004 PERIOD)

Consulting and license fee revenues for the 2005 Period increased approximately $305,000 to $344,000 from $39,000 for the 2004 Period. This revenue increase for the 2005 Period was primarily attributable to revenues from the Company s arrangements with Manhattan and Velcera, in addition to amortization of deferred revenue from license fees received.

Research and development expenses for the 2005 Period increased approximately $1,034,000 to $2,270,000 from $1,236,000 for the 2004 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 for the 2005 Period increased approximately $2,825,000 to $5,812,000 from $2,987,000 for the 2004 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 $940,000 decrease in compensation expense related to variable accounting adjustments to certain of the Company s outstanding stock options in the 2004 Period. In addition, consulting fees during the 2005 Period included a non-cash charge of $307,000 for restricted shares awarded to a consultant (see Note 5). Primarily as a result of the factors described above, total costs and expenses for the 2005 Period increased approximately $3,859,000 to approximately $8,082,000 compared to the 2004 Period.

Interest income decreased approximately $21,000 to $49,000 for the 2005 Period from $70,000 for the 2004 Period due to lower average cash and marketable investment balances in the 2005 Period as compared to the 2004 Period.

Income tax benefit for the 2005 Period was approximately $241,000 as compared to $214,000 for the 2004 Period. These benefits resulted from the sale of the Company s New Jersey net operating losses.

The resulting net loss for the 2005 Period was $7,448,000 compared to a net loss of $3,900,000 for the 2004 Period.

THE THREE MONTHS ENDED APRIL 30, 2005 (THE 2005 PERIOD) COMPARED TO THE THREE MONTHS ENDED APRIL 30, 2004 (THE 2004 PERIOD)

Consulting and license fee revenues for the 2005 Period increased approximately $86,000 to $102,000 from $16,000 for the 2004 Period. This revenue increase for the 2005 Period was primarily attributable to the Company s arrangements with Manhattan and Velcera, in addition to amortization of deferred revenue from license fees received.

Research and development expenses increased approximately $270,000 to $851,000 from $581,000 for the 2004 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 for the 2005 Period increased approximately $882,000 to $1,907,000 from $1,025,000 for the 2004 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 fees and legal costs associated with the filing of additional patent applications, increased travel and trade show attendance, and a $193,000 decrease in compensation expense related to variable accounting adjustments to certain of the Company s outstanding stock options in the 2004 Period. Primarily as a result of the factors described above, total costs and expenses for the 2005 Period increased approximately $1,152,000 to approximately $2,758,000 as compared to the 2004 Period.

Interest income decreased approximately $45,000 to $14,000 for the 2005 Period from $59,000 for the 2004 Period due to lower average cash and marketable investment balances in the 2005 Period as compared to the 2004 Period.

The resulting net loss for the 2005 Period was $2,642,000 compared to a net loss of $1,531,000 for the 2004 Period.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities approximated $4,242,000 for the 2005 Period compared to net cash used in operating activities of approximately $4,222,000 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 $7,448,000 and $3,900,000, respectively, partially offset by an increase in deferred revenue for the 2005 Period of $2,014,000 and increased by an adjustment to eliminate a noncash benefit from variable plan accounting in the 2004 Period of $969,000. The increase in deferred revenue is attributable to payments received by the Company from its licensees (see Note 6), which payments are being amortized over the remaining terms of the agreements with the licensees. Also impacting net cash used in operating activities for the 2005 Period is the $433,000 increase in inventory related to the purchase of raw materials for the Company s nitroglycerin lingual spray product candidate. For the 2005 Period, $2,574,000 was provided from investing activities, principally from the sales and maturities of investments, net of purchases of investments, which amounts exceeded capital expenditures, as compared to cash used in investing activities of $380,000 for the 2004 Period which related solely to capital expenditures. Capital expenditures for the 2005 Period totaled approximately $2,103,000 and consisted of $1,158,000 in leasehold improvements for the Company s new laboratory facility and $543,000 in manufacturing equipment at INyX for the manufacture of the Company s product candidate. The Company does not anticipate that capital expenditures in fiscal 2006 will reach the level experienced in fiscal 2005. For the 2005 Period, financing activities provided approximately $774,000, which consisted of cash received for shares issued to Hana and cash received for warrants exercised, offset by payments on a capital lease.

The Company has reported a net loss of $7,448,000 for the nine months ended April 30, 2005 and a net loss of $3,900,000 for the nine months ended April 30, 2004, as restated (see Note 3). Management believes that the Company will continue to incur net losses through at least April 30, 2006. As of April 30, 2005, the Company had working capital of $2,505,000, cash and cash equivalents of $1,272,000 and short-term investments of $2,742,000. Until and unless the Company s operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and short-term 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.

On May 26, 2005, the Company closed a private placement (the Offering) of 6,733,024 shares of common stock, and Class D warrants to purchase a total of 2,356,559 shares of common stock, with an initial exercise price equal to $1.30 per share of common stock, subject to adjustment. The Company received net proceeds of approximately $6,300,000 from the Offering. See Note 8.

Management of the Company believes that by no later than the end of the fiscal quarter ending April 30, 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. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for the nine months ended April 30, 2005 and 2004 were $2,270,000 and $1,236,000, respectively. For the third quarter 2005 Period and the 2004 Period, research and development expenses were $851,000 and $581,000, 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. 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 three and nine months ended April 30, 2005 and 2004:

	THREE MONTHS ENDED April 30,	
	2005	2004
RESEARCH AND DEVELOPMENT EXPENSES:		
Research and pre-clinical operations	$ 201,000	$ 55,000
Direct clinical trial expenses	123,000	47,000
Manufacturing development	124,000	8,000
Unallocated development	403,000	471,000
RESEARCH AND DEVELOPMENT EXPENSES	$ 851,000	$ 581,000

	NINE MONTHS ENDED April 30,	
	2005	2004
RESEARCH AND DEVELOPMENT EXPENSES:		
Research and pre-clinical operations	$ 250,000	$ 88,000
Direct clinical trial expenses	435,000	199,000
Manufacturing development	155,000	8,000
Unallocated development	1,430,000	941,000
RESEARCH AND DEVELOPMENT EXPENSES	$ 2,270,000	$ 1,236,000

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

This Current Report on Form 10-QSB includes forward-looking information about the Company, its research and development activities, its financial results and estimates, its business prospects, and its ability to obtain capital. In addition, from time to time we also may provide oral or written forward looking statements in other materials we release to the public. Forward-looking statements give our expectations or forecasts of future events at the time such statements are made. You can identify these statements by the fact that they do not relate strictly to historic or current facts. They use words such as anticipate, estimate, expect, project, intend, plan, believe, will, and other words and terms of s meaning. Among the factors that could cause actual results to differ materially are the following:

- We are a pre-commercialization company, have a limited operating history and have not generated any revenue from the sale of products to date
- The Company requires significant capital to fund the Company s operations, including the Company s research and development efforts, manufacturing requirements and clinical trials
- Additional financing requirements could result in dilution to existing stockholders
- Our technology platform is based solely on our proprietary drug delivery technology and our ongoing clinical trails for certain of our product candidates may be delayed, or fail which will harm our business
- There are certain interlocking relationships and potential conflicts of interest
- The Company does not have direct consumer marketing experience and we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third parties
- Failure or delay in complying with current Good Manufacturing Practices (cGMP) could have a material adverse effect on our business and operating results
- Failure to enter into satisfactory arrangements for the purchase from suppliers for the active ingredients used in the manufacture of our proposed pharmaceutical products could have a material adverse effect on our business and operations
- Our internal controls and procedures have been materially deficient, and we are in the process of correcting internal control deficiencies
- Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on our stock price
- Our expenses could increase due to factors outside our control as a result of changing laws, regulations and standards relating to corporate governance and public disclosure

The Company operates markets characterized by intense competition against established pharmaceutical companies

The Company could be exposed to potential product liability claims by end users of our products

Extensive and changing government regulations may affect our business

Failure to complete pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval could have a material adverse effect on our business and operations

Failure to respond to the FDA s approvable letter regarding the Company s NDA for NitroMist (nitroglycerin lingual aerosol), including completion of process validation and other work necessary to obtain final FDA approval could have a material adverse effect on our business and operations

Failure to receive necessary regulatory approvals, including final approval from the FDA for NitroMist (nitroglycerin lingual aerosol) could have a material adverse effect on our business and operations

Failure to avoid significant litigation which could affect the Company s intellectual property standing and the Company s ability to market certain product candidates could have a material adverse effect on our business and operations

Uncertainty exists over reimbursement from third party payors and healthcare reform

The commercialization and manufacture of drug product is dependent upon the performance of third-party collaborators

Failure to protect our intellectual property from use of our technology by other companies in competitive products, both in the United States and in other countries could have a material adverse effect on our business and operations. Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us. Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others.

The Company is dependent upon licensing arrangements with third parties to utilize our intellectual property rights to our products under development

The Company is reliant on confidentiality agreements that could be breached and may be difficult to enforce

The Company is controlled by current stockholders, officers and directors

Market price of our stock and our earnings may be adversely affected by market volatility; penny stock regulations may impose certain restrictions on marketability of our securities and the issuance of additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market

There is limitation on director and officer liability as permitted by Delaware law and our certificate of incorporation limits the rights of stockholders to recover against directors for breach of fiduciary duty

The Company does not have a history of paying dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future

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

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.

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.

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.

Item 3. 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 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 Chief 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 April 30, 2005, 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 Chief 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 permitted 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. See Note 3 to Notes to Condensed 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 includes increased diligence by the Company s management and directors. The Company is committed to addressing its control environment and reporting procedures.

In December 2004, the Company hired a new Chief Financial Officer and in March 2005, the Company hired a Corporate Controller. The Company believes that these hirings will improve the Company s internal controls, particularly with respect to its need to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

To address the weaknesses identified in the Company s internal controls and disclosure practices, the Company has established written disclosure controls and procedures applicable to periodic reports and certain public communications. The Company has a Disclosure Committee, which is chaired by the Company s Vice President and General Counsel and comprised of other executives. The Disclosure Committee establishes, maintains, monitors and evaluates the Company s written disclosure controls and procedures and coordinates 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, variable accounting relating to the cashless exercise feature is no longer required for substantially all of the outstanding options after the Company s fiscal quarter ended October 31, 2004. To address the weaknesses in recordkeeping related to option grants, the Company is evaluating its documentation, controls and procedures for the reconciliation of options and warrants issued by the Company.

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

Other than hiring the Corporate Controller in March 2005, there were no significant changes made in our internal controls over financial reporting during the three months ended April 30, 2005 or, to our knowledge, in other factors that have materially affected, or are materially likely to affect, these controls.

The Company has recently commenced its effort to ensure compliance with Section 404 of the Sarbanes-Oxley Act of 2002. As a non-accelerated filer with a fiscal year end of July 31, the Company must first begin to comply with the requirements of Section 404 for the fiscal year ending July 31, 2006. During the periods through July 31, 2006, we will review, and where necessary, enhance our internal control design and documentation, management review, and ongoing risk assessment as part of our internal control program.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On May 26, 2005, the Company closed a private placement (the Offering) of 6,733,024 shares of its common stock, par value $.001 per share (Common Stock) at $1.05 per share, and Class D warrants (the Warrants) to purchase a total of 2,356,559 shares of Common Stock. The Company also issued to Paramount BioCapital, who acted as its placement agent, a warrant to purchase 336,651 shares of Common Stock (the Placement Warrants). The Company received gross proceeds of $7,069,675 from the Offering.

The Offering was not registered under the Securities Act in reliance on the exceptions set forth in Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. Each of the purchasers in the Offering represented that it is an accredited investor, as defined by Rule 501 of Regulation D promulgated under the Securities Act, and certificates representing the shares of Common Stock, the Warrants and the Placement Warrants issued in connection with the Offering will contain appropriate legends to reflect the restrictions on transfer imposed by the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders.

The Company held its 2005 Annual Meeting of Stockholders on February 28, 2005. At that meeting, stockholders elected Gary A. Shangold, M.D., William F. Hamilton, Ph.D., Lawrence Jay Kessel, M.D. FACP, Mark A. Rachesky, M.D., Charles Nemeroff, M.D., Ph.D. and Robert G. Savage as Directors of the Company. The terms of these directors will expire at the 2006 Annual Meeting. In addition, stockholders approved one company proposal. The persons elected and the results of the voting are as follows:

	Votes For	Votes Withheld
Gary A. Shangold, M.D.	20,974,507	16,500
William F. Hamilton, Ph.D.	20,969,007	22,000
Lawrence Jay Kessel, M.D. FACP	20,946,507	44,500
Mark A. Rachesky, M.D.	20,974,495	16,512
Charles Nemeroff, M.D., Ph.D.	20,969,007	22,000
Robert G. Savage	20,969,007	22,000

	Votes For	Votes Against	Abstain	Broker Non-Vote
Company proposal to ratify selection of J.H. Cohn LLP as the Company s independent registered public accounting firm for the fiscal year ending July 31, 2005	20,181,078	1,000	808,929	0

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit No.	Description
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

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: June 14, 2005

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

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

Dated: June 14, 2005

By: /s/ Michael E. Spicer

Michael E. Spicer
Chief Financial Officer

28