NOVADEL PHARMA INC
Form 10-Q
March 15, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended January 31, 2006

OR

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES

EXCHANGE ACT OF 1934

For the transition period from _____ to _____ .

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.

(Name of registrant as specified in its charter)

DELAWARE	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

Registrant s telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated file, or a non-accelerated filer. See definition of accelerated filer and larger accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer o Accelerated Filer o Non-accelerated filer x

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

As of March 1, 2006, the issuer had 40,667,318 shares of Common Stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JANUARY 31, 2006

TABLE OF CONTENTS

2

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

This Current Report on Form 10-Q includes forward-looking statements , including statements regarding NovaDel Pharma Inc. s (the Company, we, us or NovaDel) expectations, beliefs, intentions or strategies for the future and the Company s internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company s views as of the date they are made with respect to future events and financial performance. In particular, the Management s Discussion and Analysis of Financial Condition and Results of Operations 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 included as Item IA in Part II of this Quarterly Report 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 JANUARY 31, 2006 (UNAUDITED) AND JULY 31, 2005

	January 31, 2006 (unaudited)	July 31, 2005 (Note 2)
ASSETS		
Current Assets:		
Cash and cash equivalents	$2,383,000	$4,680,000
Short-term investments	497,000	3,543,000
Accounts receivable from related parties, net of allowances of $100,000 at January 31, 2006 and $54,000 at July 31, 2005		108,000
Inventories	506,000	549,000
Investment in marketable equity security available for sale	468,000	
Prepaid expenses and other current assets	557,000	306,000
Total Current Assets	4,411,000	9,186,000
Property and equipment, net	2,853,000	2,991,000
Other assets	336,000	351,000
Investment in restricted equity security at cost		500,000
TOTAL ASSETS	$7,600,000	$13,028,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$390,000	$1,179,000
Accrued expenses and other current liabilities	1,288,000	1,064,000
Current portion of deferred revenue	162,000	162,000
Total Current Liabilities	1,840,000	2,405,000
Non-current portion of deferred revenue	2,592,000	2,674,000
Total Liabilities	4,432,000	5,079,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, $.001 par value:		
Authorized 100,000,000 shares, Issued 40,667,318 and 40,597,318 shares at January 31, 2006 and July 31, 2005, respectively	41,000	41,000
Additional paid-in capital	42,962,000	42,305,000
Accumulated deficit	(39,797,000)	(34,391,000)
Accumulated other comprehensive loss	(32,000)	
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)

Total Stockholders Equity	3,168,000	7,949,000
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$7,600,000	$13,028,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended January 31,		Six Months Ended January 31,	
	2006	**2005**	**2006**	**2005**
License Fees and Milestone Fees Earned from Related Parties	$ 541,000	$ 41,000	$ 582,000	$ 60,000
Consulting Revenues from Related Parties		83,000	109,000	182,000
Total Revenues	541,000	124,000	691,000	242,000
Research and Development Expenses	1,489,000	759,000	2,386,000	1,419,000
Consulting, Selling, General and Administrative Expenses	2,169,000	2,169,000	4,040,000	3,905,000
Total Expenses	3,658,000	2,928,000	6,426,000	5,324,000
Loss From Operations	(3,117,000)	(2,804,000)	(5,735,000)	(5,082,000)
Interest Income	30,000	13,000	73,000	35,000
Loss Before Income Tax Benefit	(3,087,000)	(2,791,000)	(5,662,000)	(5,047,000)
Income Tax Benefit	256,000	241,000	256,000	241,000
Net Loss	$ (2,831,000)	$ (2,550,000)	$ (5,406,000)	$ (4,806,000)
Basic and Diluted Loss Per Common Share	$ (.07)	$ $(.08)	$ (.13)	$ (.14)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Share	40,647,556	33,596,406	40,626,921	33,341,748

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JANUARY 31, 2006

(UNAUDITED)

	Common Stock						
	Shares	**Amount**	**Additional Paid In Capital**	**Accumulated Deficit**	**Accumulated Other Comprehensive Loss**	**Treasury Stock**	**Total Stockholders Equity**
BALANCE, July 31, 2005	40,597,318	$41,000	$42,305,000	$(34,391,000)	$	$(6,000)	$ 7,949,000
Stock-based compensation expense			605,000				605,000
Stock issued for options exercised	70,000		52,000				52,000
Comprehensive loss:							
Unrealized loss on investment in marketable equity security					(32,000)		(32,000)
Net loss				(5,406,000)			(5,406,000)
Total comprehensive loss							(5,438,000)
BALANCE, January 31, 2006	40,667,318	$41,000	$42,962,000	$(39,797,000)	$(32,000)	$(6,000)	$ 3,168,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JANUARY 31, 2006 AND 2005

(UNAUDITED)

		2006			**2005**	
CASH FLOWS FROM OPERATING ACTIVITIES:						
Net loss	$	(5,406,000	)	$	(4,806,000	)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock issued for services					307,000	
Warrants issued for services					11,000	
Stock-based compensation expense		605,000				
Impact of variable plan accounting					(5,000	)
Depreciation and amortization		249,000			186,000	
Bad debt expense-related parties		46,000				
Changes in operating assets and liabilities:						
Accounts receivable from related parties		62,000			(18,000	)
Inventories		43,000			(160,000	)
Prepaid expenses and other current assets		(251,000	)		(10,000	)
Other assets		15,000				
Accounts payable		(789,000	)		221,000	
Accrued expenses and other current liabilities		224,000			216,000	
Deferred revenue		(82,000	)		2,055,000	
Net cash used in operating activities		(5,284,000	)		(2,003,000	)
CASH FLOWS FROM INVESTING ACTIVITIES:						
Purchase of property and equipment		(111,000	)		(1,371,000	)
Purchase of short-term and long-term investments		(1,300,000	)		(4,280,000	)
Maturities of short-term and long-term investments		4,346,000			6,094,000	
Net cash provided by investing activities		2,935,000			443,000	
CASH FLOWS FROM FINANCING ACTIVITIES:						
Proceeds received from options exercised		52,000				
Proceeds received from warrants exercised					200,000	
Proceeds from shares of common stock issued to Hana Biosciences, Inc.					636,000	
Payments of capitalized lease obligations					(62,000	)
Net cash provided by financing activities		52,000			774,000	
NET DECREASE IN CASH AND CASH EQUIVALENTS		(2,297,000	)		(786,000	)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		4,680,000			2,166,000	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$	2,383,000		$	1,380,000	
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:						
Investment in Hana Biosciences, Inc. common stock received in connection with license agreement	$			$	500,000	

See accompanying notes to condensed financial statements.

7

NOVADEL PHARMA INC.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 NATURE OF THE BUSINESS

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

Through January 31, 2006, the Company has entered into strategic license agreements with (i) Manhattan Pharmaceuticals, Inc. (Manhattan), in connection with propofol, (ii) Velcera Pharmaceuticals, Inc. (Velcera), in connection with veterinary applications for currently marketed veterinary drugs, (iii) Par Pharmaceutical, Inc. (Par), for the marketing rights in the United States and Canada for the Company s nitroglycerin oral spray, and (iv) Hana Biosciences Inc. (Hana Biosciences), for the marketing rights in the United States and Canada for the Company s ondansetron oral spray.

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

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

NOTE 2 - BASIS OF PRESENTATION AND LIQUIDITY

The balance sheet at July 31, 2005, the end of the preceding fiscal year, has been derived from the audited balance sheet contained in the Company s Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005, and is presented for comparative purposes. All other financial statements are unaudited. The condensed financial statements are presented on the basis of accounting principles generally accepted in the United States of America for interim financial statements. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect reported loss,

financial position and various disclosures. Actual results could differ from those estimates. In the opinion of management, all adjustments, which include only normal recurring adjustments, necessary to present fairly the financial position, results of operations and cash flows for all periods presented, have been made in the interim financial statements. Results of operations for interim periods are not necessarily indicative of the operating results to be expected for a full fiscal year.

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

The Company has reported a net loss of $5,406,000 for the six months ended January 31, 2006 and a net loss of $4,806,000 for the six months ended January 31, 2005. As of January 31, 2006, the Company had working capital of $2,571,000, cash and cash equivalents of $2,383,000 and short-term investments of $497,000. Until and unless the Company s operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company s long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of its equity or debt securities or bridge loans to the Company from third party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. In our Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005 and our Quarterly Report on Form 10-Q for the quarter ended October 31, 2005, we stated that unless we received additional capital during the fiscal year ended July 31, 2006, we would have to significantly reduce our operating expenses in order to have sufficient cash to fund our operations through the end of fiscal 2006. As of March 15, 2006, we have not received additional capital and we have not significantly reduced our operating expenses. 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. The Company is in the process of reviewing alternatives to secure additional capital and we expect to have consummated a transaction by no later than April 30, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. There are a number of risks and uncertainties related to the Company s attempt to complete a financing or strategic partnering arrangement that are outside the control of the Company. The Company may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

NOTE 3 INVENTORIES

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

Inventories at January 31, 2006 and July 31, 2005 primarily consisted of raw materials related to the Company s nitroglycerin lingual aerosol product candidate. Through outsourcing to INyX, the Company is in the process of starting to make commercial quantities for this product candidate prior to the date that such product candidate may receive final U.S. Food and Drug Administration (FDA) marketing approval (i.e., pre-launch inventory). On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol). The Company believes that the FDA is likely to give final approval once the Company completes its previously agreed to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. If final approval of this product candidate is not received, or approval is not received timely compared to our estimates for product shelf-life, the Company will write-off the related amounts of pre-launch inventory in the period of that determination. If the Company had been required to write-off the $506,000 and $549,000 recorded as pre-launch inventory at January 31, 2006 and July 31, 2005, respectively, these amounts would have been considered by the Company to have been material to its operating results and are likely to be considered material if such write-offs are required in a subsequent period.

NOTE 4 CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

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

NOTE 5 - LOSS PER SHARE

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 January 31, 2006 and July 31, 2005, there were 27.7 million and 26.2 million common shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per share computation.

NOTE 6 - STOCK-BASED COMPENSATION

At January 31, 2006, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan and the 2006 Equity Incentive Plan (the Plans). On January 17, 2006, the stockholders of the Company, upon recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the 2006 Plan). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The amount of shares to be reserved for issuance under the 2006 Plan is 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options (ISOs) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company s common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years.

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

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

Information with respect to stock option activity for the six months ended January 31, 2006 is as follows:

	Outstanding Options	
	Number of Options	
	(in thousands)	**Weighted Average Exercise Price**
Balance at August 1, 2005	6,474	$1.64
Grants	2,660	1.58
Exercises	(70)	.75
Cancellations	(916)	1.66
Balance at January 31, 2006	8,148	$1.62

For grants during the six months ended January 31, 2006, the Company s weighted average assumptions used in determining fair value under the Black-Scholes model for expected volatility, dividends, expected term until exercise, and risk-free interest rate were 64%, 0%, 5.5 years and 4.1%, respectively. Expected volatility is based on historical volatility of the Company s common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In the three and six months ended January 31, 2006, the Company recorded share-based compensation for options of approximately $255,000 or $.01 per share and $605,000 or $.01 per share, respectively, which is included in the Company s net loss for each period.

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

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

The following table illustrates the pro forma effect on the Company s net loss and net loss per share as if the Company had adopted the fair-value-based method of accounting for stock-based compensation under SFAS 123 for the three and six months ended January 31, 2005:

	Three Months Ended January 31, 2005
Net loss as reported	$(2,550,000)
Compensation expense resulting from variable plan accounting	(34,000)
Total stock-based employee compensation expense using the fair value based method for all awards	(197,000)
Pro forma net loss	$(2,781,000)
Basic and diluted net loss per common share:	
As reported	$(.08)
Pro forma net loss	$(.08)

	Six Months Ended January 31, 2005
Net loss as reported	$(4,806,000)
Compensation expense resulting from variable plan accounting	(5,000)
Total stock-based employee compensation expense using the fair value based method for all awards	(368,000)
Pro forma net loss	$(5,179,000)
Basic and diluted net loss per common share:	
As reported	$(.14)
Pro forma net loss	$(.16)

The fair values of options granted during the six months ended January 31, 2005 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company s common stock of 68% and an expected life of the options of five to ten years.

NOTE 7 RELATED PARTY TRANSACTIONS AND LICENSE AND DEVELOPMENT AGREEMENTS

License and Development Agreements with Related Parties

In April 2003, the Company entered into a license and development agreement with Manhattan, a related party, for the worldwide, exclusive rights to the Company s proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first $125,000 of which was partially received during June 2003. During the three months ended January 31, 2006 and 2005, the Company invoiced Manhattan approximately $0 and $20,000, respectively, for the Company s reimbursable expenses. During the six months ended January 31, 2006 and 2005, the Company invoiced Manhattan approximately $0 and $120,000, respectively, for the Company s reimbursable expenses. In November 2003, the Company received $375,000 from Manhattan for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company and related party. The license agreement is for the exclusive rights to the Company s propriety oral spray technology in animals. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received 529,500 shares of common stock of Velcera, approximately 15% of the outstanding shares at the time the shares were issued which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the three months ended January 31, 2006 the Company recorded a $46,000 charge to consulting, selling, general and administrative expenses to establish a reserve for past due accounts receivable from Velcera. During the three months ended January 31, 2005, the Company invoiced Velcera approximately $63,000 for reimbursable expenses. During the six months ended January 31, 2006 and 2005, the Company invoiced Velcera approximately $109,000 and $63,000, respectively, for reimbursable expenses.

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences, a related party, an exclusive license to develop and market the Company s oral spray version of ondansetron, an anti-emetic, in the United States and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences 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 Biosciences issued to the Company $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. In December 2005, upon Hana Bioscience s submission of its Investigational New Drug (IND) Application for Zensana , its lingual spray version of ondansetron, the Company received a $500,000 milestone payment from Hana Biosciences.

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.

Other License and Development Agreements

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

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

NOTE 8 INVESTMENT IN EQUITY SECURITY

As explained in Note 7, in October 2004, as part of the license agreement with Hana, the Company received $500,000 of common stock of Hana (73,121 shares based on a market value of $6.84 per share at the date of the agreement). As a result of restrictions on its ability to sell the shares, the Company was required by SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, to account for those shares using the cost method through October 2005 and thereafter as marketable equity securities. At January 31, 2006, the Company has classified the shares as available for sale and is recording changes in their value as part of its comprehensive loss. Such shares had a market value of $468,000 at January 31, 2006 and, accordingly, the Company has included its $32,000 unrealized loss in accumulated other comprehensive loss for the six month period then ended. At January 31, 2006, the Company believes the decrease in the fair value of these shares to be temporary and no charge for impairment in the statement of operations is required.

NOTE 9 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 $256,000 and $241,000 for the three and six months ended January 31, 2006 and 2005, respectively, from the sale of its New Jersey net operating losses. The income tax benefit recorded in the three and six months period ended January 31, 2006, was derived from the sale of $3,273,000 of New Jersey net operating losses. If still available under New Jersey law, the Company may attempt to sell our 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 it 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 10 THREATENED LITIGATION

In January 2005, we granted 160,000 restricted common shares to a consultant as consideration for services to be rendered in the future by the consultant. In February 2006, we were approached by the consultant s attorney with a request to lift the restriction on the stock certificate. We declined to lift that restriction pursuant to Rule 144(d)(1) of the General Rules and Regulations promulgated under the Securities Act of 1933, as the one-year period for holding that restriction did not begin until December 2005, the date the consultant s services ended. The consultant s attorney has threatened litigation to have such restriction lifted.

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

COMPANY OVERVIEW

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

Since inception, substantially all of our revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. More recently, we have begun to derive revenues from license fees and milestone payments stemming from its partnership agreements. The future growth and profitability of the Company will be principally dependent upon its ability to successfully develop its products and to market and distribute the final products either internally or with the assistance of a strategic partner.

Recent highlights include the following product development and business achievements:

Completed two pre-Investigational New Drug Application (IND) meetings with the Food and Drug Administration (FDA), including meetings for the Company s sumatriptan (Imitrex®) and zolpidem (Ambien®) product candidates. In addition, NovaDel participated in a pre-IND meeting with its partner Hana Biosciences, Inc. (Hana Biosciences) for the ondansetron (Zofran®) (Zensana) product candidate.

Filing of IND for ondansetron (Zensana) by our partner, Hana Biosciences, Inc.

Announcement by our partner, Hana Biosciences, of positive study results of a pivotal clinical trial for Zensana Ondansetron Oral Spray, a study which definitively demonstrated Zensana 8mg dose is bioequivalent to the current commercially available 8mg tablet (Zofran®).

Addition of Jan Egberts, M.D. who assumed the positions of President and Chief Executive Officer on December 23, 2005 and Chairman of the Board on January 17, 2006.

Issuance of two patents by the U.S. Patent and Trademark Office that further strengthens our intellectual property position in the oral delivery of pharmaceuticals. The issued patents cover the use of multiple classes of drugs in oral sprays, including those for the treatment of pain, central nervous system disorders, and for anesthesia under our oral spray delivery system.

Over the next fiscal year, we expect to devote the majority of our internal research and development resources to the following product candidates:

Nitroglycerin. On June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist (nitroglycerin lingual aerosol). We believe that the FDA is likely to give final approval once we complete our previously agreed-to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. In our Form 10-Q filed for the quarter ended October 31, 2005, we indicated that we anticipated completing our process validation commitments in the first calendar quarter of 2006. However, we are currently planning to complete our process validation commitments in the second calendar quarter of 2006. If this

timeline is met, we may obtain final approval from the FDA by the end of the second calendar quarter of 2006, which target was not affected by the delay in completing our process validation commitments.

Zolpidem. We had a pre-IND meeting with the FDA on August 31, 2005 and anticipate filing the IND during the third quarter of calendar year 2006. In our Form 10-Q filed for the quarter ended October 31, 2005, we indicated that we anticipated filing the IND during the first quarter of calendar year 2006. However, the FDA has required that we complete certain studies prior to IND submission, and we have therefore delayed the filing of such IND pending completion of those studies. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the zolpidem oral spray product. We are currently targeting a NDA submission for our zolpidem product candidate in the first quarter of calendar 2007, which target was not affected by the delay in the IND filing.

Sumatriptan. We had a pre-IND meeting with the FDA on August 10, 2005, and filed the IND in December 2005. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the sumatriptan oral spray product. We are currently targeting a NDA submission for our sumatriptan product candidate in the third quarter of calendar 2007.

Unspecified. We have identified a number of additional product candidates for which we have recently commenced preliminary development activities.

We will also support our partners, as necessary, with the following product candidates and opportunities although we do not expect to devote a significant amount of resources to such activities.

Ondansetron. Our partner for this product, Hana Biosciences, filed the IND in November 2005. Subsequent to the IND submission, Hana Biosciences plans to execute the clinical protocol and administer clinical trials for the ondansetron oral spray product, Zensana , and is planning to submit its NDA in May 2006. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . While Hana Biosciences has the rights to the ondansetron product candidate in the United States and Canada, NovaDel retains the rights in the rest of the world.

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

Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals, Inc. (Velcera).

In the Form 10-Q filed for the quarter ended October 31, 2005, we indicated plans to request a pre-IND meeting with the FDA for our alprazolam product candidate, with an anticipated goal of filing the IND during the first half of calendar year 2006. Following the IND meeting, we were planning to execute the clinical protocol and administer clinical trials for the alprazolam oral spray product candidate. We have since determined that, in order to devote sufficient resources to other projects noted above, it is appropriate to defer further efforts on alprazolam. As a result, we are not currently scheduling a pre-IND meeting with the FDA, nor do we contemplate a specific timeframe for submitting an IND, pending further review.

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

CRITICAL ACCOUNTING POLICIES

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

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

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

The Company has adopted the provisions of SFAS 123R effective August 1, 2005 and has selected the Black-Scholes method of valuation for share-based compensation. The Company has adopted the modified prospective transition method which requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Prior to the adoption of SFAS 123R, the Company applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended, which were similar in most respects to SFAS 123R. For the three and six months ended January 31, 2006, we recorded share-based compensation of approximately $255,000 or $.01 per share and $605,000 or $.01 per share, respectively. We will continue to incur share-based compensation charges in future periods. For the three and six months ended January 31, 2005, the pro forma effect on the Company s net loss and net loss per share as if the Company had adopted the fair value-based method of accounting for stock-based compensation under SFAS 123 was $191,000 or $.01 per share and $368,000 or $.01 per share, respectively.

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

RESEARCH AND DEVELOPMENT EXPENSES - Research and development expenses are expensed as incurred.

RESULTS OF OPERATIONS

SIX MONTHS ENDED JANUARY 31, 2006 AND 2005

License fees and milestone fees earned from related parties for the six months ended January 31, 2006 were $582,000, as compared to $60,000 for the six months ended January 31, 2005. The $522,000 increase is primarily due to a $500,000 milestone payment received from Hana Biosciences, Inc. in the six months ended January 31, 2006 upon submission of Hana Bioscience s IND for Zensana .

Consulting revenues from related parties for the six months ended January 31, 2006 were $109,000 as compared to $182,000 for the six months ended January 31, 2005. The $73,000 decrease is primarily due to decreased revenue associated with our arrangements with Velcera and Manhattan.

Research and development expenses for the six months ended January 31, 2006 were $2,386,000, as compared to $1,419,000 for the six months ended January 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The increase in research and development expenses is primarily related to the following items:

- $344,000 increase primarily related to product development costs for the Company s Zolpidem (Ambien®) product candidate;
- $159,000 increase due to costs incurred in conjunction with the clinical trials for Zensana conducted by our partner, Hana Biosciences;
- $231,000 increase related to process validation and method transfer activities for our NitroMist product candidate; and
- $184,000 increase related to higher lab supplies expense.

Consulting, selling, general and administrative expenses for the six months ended January 31, 2006 were $4,040,000 as compared to $3,905,000 for the six months ended January 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The slight increase in consulting, selling, general and administrative costs is primarily related to the following items:

- $138,000 charge related to severance costs for one of our former officers;
- $545,000 non-cash charge in the six months ended January 31, 2006 for stock-compensation expense;
- $152,000 decrease in outside consultant legal costs;
- $307,000 decrease attributable to a non-cash charge recorded in the six months ended January 31, 2005 for restricted shares of our common stock awarded to a consultant; and
- The remaining decrease, net of individually offsetting items of lesser significance, is primarily attributable to lower consultants expenses.

Primarily as a result of the factors described above, total costs and expenses for the six months ended January 31, 2006 were $6,426,000 as compared to $5,324,000 for the six months ended January 31, 2005.

Interest income for the six months ended January 31, 2006 was $73,000 as compared to $35,000 for six months ended January 31, 2005 due to a general increase in interest rates.

Income tax benefit for the six months ended January 31, 2006 was $256,000 as compared to $241,000 for the six months ended January 31, 2005.

The resulting net loss for the six months ended January 31, 2006 was $5,406,000 as compared to $4,806,000 for the six months ended January 31, 2005.

THREE MONTHS ENDED JANUARY 31, 2006 AND 2005

License fees and milestone fees earned from related parties for the three months ended January 31, 2006 were $541,000, as compared to $41,000 for the three months ended January 31, 2005. The $500,000 increase is due to a $500,000 milestone payment received from Hana Biosciences in the three months ended January 31, 2006 upon submission of Hana Biosciences s IND for Zensana .

Consulting revenues from related parties for the three months ended January 31, 2006 were $0 as compared to $83,000 for the three months ended January 31, 2005. The decrease is due to no revenue associated with our arrangements with Manhattan and Velcera being recognized in the three months ended January 31, 2006.

Research and development expenses for the three months ended January 31, 2006 were $1,489,000, as compared to $759,000 for the three months ended January 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The increase in research and development expenses is primarily related to the following items:

- $219,000 increase primarily related to product development costs for our Zolpidem (Ambien®) product candidate;
- $159,000 increase due to costs incurred in conjunction with the clinical trials for Zensana conducted by our partner, Hana Biosciences;
- $231,000 increase related to process validation and method transfer activities for our NitroMist product candidate; and
- $90,000 increase related to higher lab supplies expense.

Consulting, selling, general and administrative expenses for the three months ended January 31, 2006 remained flat at $2,169,000 as compared to the three months ended January 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. While consulting, selling, general and administrative costs remained flat, the following items represent the more significant fluctuations:

- $210,000 non-cash charge in the three months ended January 31, 2006 for stock-compensation expense; and
- $307,000 decrease attributable to a non-cash charge recorded in the three months ended January 31, 2005 for restricted shares of our common stock awarded to a consultant.

Primarily as a result of the factors described above, total costs and expenses for the three months ended January 31, 2006 were $3,658,000 as compared to $2,928,000 for the three months ended January 31, 2005.

Interest income for the three months ended January 31, 2006 was $30,000 as compared to $13,000 for the three months ended January 31, 2005 due to a general increase in interest rates.

Income tax benefit for the three months ended January 31, 2006 was $256,000 as compared to $241,000 for the three months ended January 31, 2005.

The resulting net loss for the three months ended January 31, 2006 was $2,831,000 as compared to $2,550,000 for the three months ended January 31, 2005.

LIQUIDITY AND CAPITAL RESOURCES

From our inception, our principal sources of capital have been consulting revenues, private placements and a public offering of its securities, as well as loans and capital contributions from our principal stockholders. We have had a history of recurring losses, giving rise to an accumulated deficit at January 31, 2006 of $39,797,000. At January 31, 2006, we had working capital of approximately $2,571,000 as compared to working capital of $6,781,000 at July 31, 2005, representing a net decrease in working capital of approximately $4,210,000. As explained further below, such decrease is primarily attributable to a decrease in cash, short-term investments and accounts payable, and an increase in prepaid expenses. In May 2005, we successfully closed an offering of our common stock and warrants to purchase shares of our common stock (Private Placement). The Private Placement involved the sale of approximately 6,733,024 shares of common stock, and warrants to purchase 2,356,559 shares of common stock. We received proceeds, net of offering costs, of approximately $6,309,000.

Net cash used in operating activities was approximately $5,284,000 for the six months ended January 31, 2006, as compared to $2,003,000 for the six months ended January 31, 2005. Net cash used in operating activities for both the six months ended January 31, 2006 and 2005 were significantly affected by the net loss of $5,406,000 and $4,806,000, respectively, partially offset by an increase in deferred revenue in the six months ended January 31, 2005 of $2,055,000. This increase in deferred revenue was attributable to payments received by us from our licensees, which payments are being amortized over the remaining terms of the agreements with the licensees. The following other significant items also impacted net cash used in operating activities in the six months ended January 31, 2006 and 2005:

$789,000 decrease in accounts payable in the six months ended January 31, 2006 primarily due to the payment of invoices included in accounts payable at July 31, 2005 related to the manufacturing and process development of our nitroglycerin product candidate, NitroMist

$251,000 increase in prepaid expenses and other current assets in the six months ended January 31, 2006 primarily attributable to the prepayment of a portion of the process validation batches for our nitroglycerin product candidate, NitroMist

$605,000 non-cash charge in the six months ended January 31, 2006 to record stock-compensation expense associated with SFAS 123R; and

$307,000 non-cash charge recorded in the six months ended January 31, 2005 for restricted shares of our common stock awarded to a consultant.

In the six months ended January 31, 2006, $2,935,000 was provided by investing activities, principally from the maturities of short-term investments, net of purchases of short-term investments. In the six months ended January 31, 2005, $443,000 was provided by investing activities which related to $6,094,000 of maturities of short-term and long-term investments, $4,280,000 of purchases of short-term and long-term investments, and $1,371,000 of capital expenditures. Capital expenditures for the six months ended January 31, 2005 consisted primarily of leasehold improvements for our new laboratory facility and manufacturing equipment at INyX for the manufacture of our NitroMist product candidate.

Cash provided by financing activities was approximately $52,000 in the six months ended January 31, 2006, as compared to $774,000 in the six months ended January 31, 2005. The $722,000 decrease is primarily due to the six months ended January 31, 2005 including $636,000 related to the proceeds received from the shares of common stock issued to Hana Biosciences.

Until and unless our operations generate significant revenues, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans from third party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. In our Annual Report on form 10-KSB for the fiscal year ended July 31, 2005 and our Quarterly Report on Form 10-Q for the quarter ended October 31, 2005, we stated that unless we received additional capital during the fiscal year ended July 31, 2006, we would have to significantly reduce our operating expenses in order to have sufficient cash to fund our operations through the end of fiscal 2006. As of March 15, 2006, we have not received additional capital and we have not significantly reduced our operating expenses. We believe that no later than the fiscal quarter ending April 30, 2006, it will be necessary for us to obtain additional financing and/or consummate a strategic alliance with a business partner. We are in the process of reviewing alternatives to secure additional capital and we expect to have consummated a transaction by no later than April 30, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

OFF-BALANCE SHEET ARRANGEMENTS

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

CONTRACTUAL OBLIGATIONS

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES.

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 Rules and Forms of the Securities and Exchange Commission (SEC). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to the Company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of January 31, 2006. Based on this evaluation, the Company s Chief Executive Officer and its Chief Financial Officer concluded that as of the end of the period covered by this report, the Company s disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

Our management, including our Chief Executive Officer and 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.

Changes in Internal Controls

During the three months ended January 31, 2006, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In January 2005, we granted 160,000 restricted common shares to a consultant as consideration for services to be rendered in the future by the consultant. In February 2006, we were approached by the consultant s attorney with a request to lift the restriction on the stock certificate. We declined to lift that restriction pursuant to Rule 144(d)(1) of the General Rules and Regulations promulgated under the Securities Act of 1933, as the one-year period for holding that restriction did not begin until December 2005, the date the consultant s services ended. The consultant s attorney has threatened litigation to have such restriction lifted.

ITEM 1A. RISK FACTORS

RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, in our Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005, and in any documents incorporated in this report by reference.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

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

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

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

We had an accumulated deficit as of January 31, 2006 of approximately $39.8 million. We incurred losses in each of our last nine fiscal years, including a net loss of approximately $9.5 million for the fiscal year ended July 31, 2005, and a net loss of $5.4 million for the six months ended January 31, 2006. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION

The research, development, testing and approval of our proposed products involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans from third party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. In our Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005 and our Quarterly Report on Form 10-Q for the quarter ended October 31, 2005, we stated that unless we received additional capital during the fiscal year ended July 31, 2006, we would have to significantly reduce our operating expenses in order to have sufficient cash to fund our operations through the end of fiscal 2006. As of March 15, 2006, we have not received additional capital and we have not significantly reduced our operating expenses. Management believes that no later than the fiscal quarter ending April 30, 2006, it will be necessary for us to obtain additional financing and/or consummate a strategic alliance with a business partner. We are in the process of reviewing alternatives to secure additional capital and we expect to have consummated a transaction by no later than April 30, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

OUR ADDITIONAL FINANCING REQUIREMENTS COULD RESULT IN DILUTION TO EXISTING STOCKHOLDERS.

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 100,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. See Risk Factors Additional Authorized Shares of Common Stock and Preferred Stock Available for Issuance May Adversely Affect the Market for a description of certain rights of Paramount BioCapital that may negatively impact our ability to raise additional capital.

OUR TECHNOLOGY PLATFORM IS BASED SOLELY ON OUR PROPRIETARY DRUG DELIVERY TECHNOLOGY. OUR ONGOING CLINICAL TRIALS FOR CERTAIN OF OUR PRODUCT CANDIDATES MAY BE DELAYED, OR FAIL, WHICH WILL HARM OUR BUSINESS.

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our 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.

We filed an NDA for our nitroglycerin lingual spray, NitroMist , on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act (PDUFA) date of June 4, 2005, for NitroMist , and received an approvable letter from the FDA on June 2, 2005. We believe that the FDA is likely to give final approval of NitroMist once we complete certain manufacturing process validation commitments which we had previously agreed to with the FDA. The FDA is not requiring us to complete any additional clinical studies for approval. Although we currently intend to complete the manufacturing process validation commitments, the FDA may not grant us final marketing approval for NitroMist if we do not timely complete the manufacturing process validation commitments or for other reasons. On June 1, 2005, we received an approvable letter from the FDA regarding its NDA for NitroMist . We are currently planning to complete our process validation commitments in the second calendar quarter of 2006; and, if this timeline is met, we may obtain final approval from the FDA by the end of the second calendar quarter of 2006. NitroMist is a trademark of Par Pharmaceuticals, Inc.

We have initiated and completed pharmacokinetic studies of our priority products during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, alprazolam, propofol and zolpidem. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific oral spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If blood levels are not achieved, it could result in the need to reformulate the oral spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

We have also completed pilot pharmacokinetic studies for two antihistamine oral sprays (loratadine and clemastine), an estradiol oral spray and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on loratadine, clemastine, estradiol and progesterone has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, companies may be unable to enroll patients quickly enough to meet expectations for completing clinical trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of NovaDel, is the Chairman and sole shareholder of Paramount BioCapital Inc. (Paramount). In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald and his affiliates may be deemed to beneficially own approximately 28% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald and his affiliates). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on the Company s Board of Directors (Board) and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell is not deemed to be an independent director. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald nor Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

OUR BUSINESS AND REVENUE IS DEPENDENT ON THE SUCCESSFUL DEVELOPMENT OF OUR PRODUCTS.

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability successfully to raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our proposed products. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our proposed products and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. See Risk Factors - We Will Require Significant Capital For Product Development And Commercialization And - Our Strategy Is To Enter Into Collaboration Agreements With Third Parties And We May Require Additional Collaboration Agreements . If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products .

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until the third calendar quarter of 2006 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. Any one or more of our proposed proprietary products may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our proposed products and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such products must be obtained before the proposed products will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps in calendar year 2006 or thereafter. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our proposed products or develop such proposed products on a timely basis. Further, such proposed products may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any proposed product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

We have no experience in marketing or distribution at the consumer level of our proposed products. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third parties. Except for our agreements with Par Pharmaceutical, Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our proposed products. We may not be able to enter into any such agreements or similar arrangements in the future and we may not be able to successfully market our products. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

We have stated our intention to market our own products in the future, although we have no such experience to date. Substantial investment will be required in order to build infrastructure and provide resources in support of marketing our own products, particularly the establishment of a marketing force. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. The establishment of our own marketing force, or a strategy to rely on third party marketing arrangements, could adversely affect our profit margins.

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

The manufacture of our pharmaceutical products under development will be subject to current Good Manufacturing Practices (cGMP) prescribed by the FDA, pre-approval inspections by the FDA or comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable foreign authorities in connection with the manufacture of our proposed products. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on our business and operations.

WE ARE DEPENDENT ON OUR SUPPLIERS.

We believe that the active ingredients used in the manufacture of our proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our proposed products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX, who intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of Dynamit Nobel or INyX to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

OUR INTERNAL CONTROLS AND PROCEDURES HAVE BEEN MATERIALLY DEFICIENT, AND WE ARE BEGINNING THE PROCESS OF CORRECTING INTERNAL CONTROL DEFICIENCIES.

In October 2004, we and our independent registered public accounting firm recognized that our internal controls had material weaknesses. These material weaknesses led in part to the delay in the production of our audited financial statements for fiscal 2004. We have restated our results of operations for the fiscal years ended July 31, 2003, and July 31, 2002, and for our quarterly results in fiscal years 2004, 2003 and 2002. Our independent registered public accounting firm advised us of material weaknesses noted during its audit of our 2004 financial statements.

If we cannot rectify these material weaknesses through remedial measures and improvements to our systems and procedures, management may encounter difficulties in timely assessing business performance and identifying incipient strategic and oversight issues. In December 2004, we hired a new Chief Financial Officer and in March 2005, we hired a Corporate Controller. We believe that these hirings have improved and will continue to improve our internal controls, particularly with respect to our need to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

We will apply resources at all relevant managerial levels toward the task of improving our internal control environment. We cannot provide assurances as to the timing of the completion of these efforts or estimates of the prospective costs of these efforts, either in dollar terms or in the form of management attention. We cannot be certain that the measures we take will ensure that we implement and maintain adequate internal controls in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

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.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the stock price of our common stock.

COMPLIANCE WITH CHANGING REGULATION OF CORPORATE GOVERNANCE AND PUBLIC DISCLOSURE MAY RESULT IN ADDITIONAL EXPENSES.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission and American Stock Exchange (AMEX) rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our independent registered public accounting firm s audit of that assessment will require the commitment of significant financial and managerial resources. In addition, it has become more difficult and more expensive for us to obtain director and officer liability insurance. We expect these efforts to require the continued commitment of significant resources. Further, our board members, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed.

WE FACE INTENSE COMPETITION.

The markets which we intend to enter are characterized by intense competition. We, or our licensees, may be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are similar to our products. If we cannot receive third party reimbursement for our products, we may not be able to commercialize our products. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We are aware of several companies that are selling or developing oral spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an air propelled dispensing system (our nitroglycerin lingual spray is a propellant based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist device. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Generex is listed as the assignee on 15 United States patents. RapidMist is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the United Kingdom, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis (MS) and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Arakis Ltd., based in the United Kingdom, also claims to be developing an analgesic to be delivered suborally via a non-pressurized metered dose spray formulation.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.

We may be exposed to potential product liability claims by end-users of our products. Although we obtain product liability insurance per contractual obligations, before the commercialization of any of our proposed products, we cannot guarantee such insurance will be sufficient to cover all possible liabilities to which we may be exposed. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our proposed products, which could have a material adverse effect on us.

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act (the FFDCA), as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product s safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND, pursuant to which permission is sought to begin preliminary clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug. We believe that the products we develop in spray dosage form will require the submission of an NDA, which may be based upon published safety and efficacy studies conducted by others, which is referred to as a 505(b)(2) NDA. We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes two to three years for the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business.

THE CLINICAL TRIAL AND REGULATORY APPROVAL PROCESS FOR OUR PRODUCTS IS EXPENSIVE AND TIME CONSUMING, AND THE OUTCOME IS UNCERTAIN.

In order to sell our proposed products, we must receive separate regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. Clinical trials generally take two to five years or more to complete. Even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept an NDA submitted by a pharmaceutical or biotechnology company for such drug product for filing, or if accepted for filing, may not approve such NDA.

On June 1, 2005, we received an approvable letter from the FDA regarding its NDA for its nitroglycerin lingual aerosol, indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We believe that the FDA will give final approval once we complete our previously agreed to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. We are currently planning to complete our process validation commitments in the second calendar quarter of 2006 and, if this timeline is met, we may obtain final approval from the FDA by the end of the second calendar quarter of 2006.

We had a pre-IND meeting with the FDA on August 10, 2005, and filed the IND in December 2005 for our sumatriptan oral spray product. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the sumatriptan oral spray product. We are currently targeting a NDA submission in the third quarter of calendar 2007.

29

We had a pre-IND meeting with the FDA on August 31, 2005 and anticipate filing the IND during the third quarter of calendar year 2006 for our zolpidem oral spray product. In our 10-Q filed for the quarter ended October 31, 2005, we indicated that we anticipated filing the IND during the first quarter of calendar year 2006. However, the FDA has required that we complete certain studies prior to IND submission, and we have therefore delayed the filing of such IND pending completion of those studies. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the zolpidem oral spray product. We are currently targeting a NDA submission for its zolpidem product candidate in the first quarter of calendar 2007, which target was not affected by the delay in the IND filing.

Our partner for the ondansetron oral spray product, Hana Biosciences, filed the IND in November 2005. Subsequent to the IND submission, Hana plans to execute the clinical protocol and administer clinical trials for the ondansetron oral spray product, Zensana , and is planning to submit its NDA in May 2006. While Hana has the rights to the ondansetron product candidate in the United States and Canada, NovaDel retains the rights in the rest of the world.

In the 10-Q filed for the quarter ended October 31, 2005, we indicated plans to request a pre-IND meeting with the FDA with an anticipated goal of filing the IND during the first half of calendar year 2006 for the alprazolam oral spray product. Following the IND meeting, we were planning to execute the clinical protocol and administer clinical trials for the alprazolam oral spray product. We have since determined that, in order to devote sufficient resources to other projects noted above, it is appropriate to defer further efforts on alprazolam. As a result, we are not currently scheduling a pre-IND meeting with the FDA, nor do we contemplate a specific timeframe for submitting an IND, pending further review.

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

Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals.

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

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may fail to reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects.

The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve any one or more of our products under development, we will not be able to market such products.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payers, which include government health administration authorities, managed care providers and private health insurers. Third party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

OUR STRATEGY IS TO ENTER INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PROPOSED PRODUCTS.

Our strategy for the completion of the required development and clinical testing of our proposed products and for the manufacturing, marketing and commercialization of such products depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products. We have entered into a license agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation; an exclusive worldwide license for our proprietary oral spray technology with Velcera Pharmaceuticals for the development of innovative veterinary medicines pursuant to which we are entitled to milestone payments for each product developed by Velcera and royalties on product sales and Velcera will fund all development and regulatory expenses; a license and supply agreement with Par Pharmaceutical pursuant to which Par Pharmaceutical has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the United States and Canada; and a license agreement with Hana Biosciences for the marketing rights in the United States and Canada for our ondansetron oral spray. Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of the products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, OTHER COMPANIES COULD USE OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OTHER COMPANIES COULD PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS.

We seek patent protection for our technology so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect our trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

We have received a request for information from a third party in response to the information we have set forth in the paragraph IV certification of the NDA we have filed for NitroMist. Such request no longer has any effect on PDUFA dates for such NDA. However, the request may be a precursor for a patent infringement claim by such third party. We do not believe that we have infringed on any intellectual property rights of such party and if such a claim is filed, we intend to vigorously defend our rights in response to such claim.

31

EVEN IF WE OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE SUFFICIENTLY BROAD AND OTHERS COULD COMPETE WITH US.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. We currently have seven patents issued in the United States and seven patents issued outside of the United States. In addition, we have approximately 120 patents pending worldwide. Our pending patent applications, those we may file in the future and those we may license from third parties may not result in the United States Patent and Trademark Office or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also Risk Factors - If we cannot meet requirements under our license agreements, we could lose the rights to our products .

INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES COULD LIMIT OUR ABILITY TO MARKET OUR PRODUCTS.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

IF WE CANNOT MEET REQUIREMENTS UNDER OUR LICENSE AGREEMENTS, WE COULD LOSE THE RIGHTS TO OUR PRODUCTS.

We depend, in part, on licensing arrangements with third parties to maintain the intellectual property rights to our products under development. These agreements may require us to make payments and/or satisfy performance obligations in order to maintain our rights under these licensing arrangements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

WE RELY ON CONFIDENTIALITY AGREEMENTS THAT COULD BE BREACHED AND MAY BE DIFFICULT TO ENFORCE.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

they will breach these agreements;

any agreements we obtain will not provide adequate remedies for this type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and

our competitors will independently discover our proprietary information and trade secrets.

WE ARE DEPENDENT ON EXISTING MANAGEMENT.

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

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

On September 28, 2005, the Board announced its appointment of Dr. Jan H. Egberts as our Chief Operating Officer, effective September 26, 2005, reporting to the Chairman of the Board. Dr. Egberts assumed the positions of President and Chief Executive Officer on December 23, 2005 and Chairman of the Board on January 17, 2006.

On October 19, 2005, our Board of Directors appointed Dr. William F. Hamilton as Chairman of the Corporate Governance and Nominating Committee. On January 17, 2006, we announced that Dr. Hamilton had been named to the newly-created position of Lead Independent Director.

On November 22, 2005, we announced that Board of Directors member, and non-executive Chairman of the Board, Mr. Robert G. Savage announced his intention not to stand for re-election to our board at the Company's 2006 annual meeting of shareholders. Mr. Savage served as a director of the Company since 2004 and as our non-executive Chairman of the Board since September 2, 2005.

On December 15, 2005, we announced that Board of Directors member, Dr. Mark Rachesky, announced his resignation from our Board. Dr. Rachesky served as a director of the Company since 2003.

In our annual proxy statement, we announced that Dr. Lawrence J. Kessel was not being nominated to stand for re-election to our Board at the Company s 2006 annual shareholders meeting. Dr. Kessel served as a Director since March 2003.

On December 15, 2006, we announced the election of Mr. J. Jay Lobell as a member of our Board of Directors effective December 14, 2005. Mr. Lobell was appointed as a result of Dr. Rosenwald s right to designate a director nominee for the Company s Board.

On January 17, 2006, we announced the election of Mr. Steven B. Ratoff as a member of our Board of Directors.

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

WE ARE CONTROLLED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. Management and our affiliates currently beneficially own (including shares they have the right to acquire) greater than 30% of the common stock on a fully-diluted basis. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Moreover, Dr. Rosenwald has the ability to designate an individual to serve on the Company s Board of Directors. He has not exercised such right; however, he may do so in the future. Such positions may discourage or prevent any proposed takeover of NovaDel, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

THE MARKET PRICE OF OUR STOCK AND OUR EARNINGS MAY BE ADVERSELY AFFECTED BY MARKET VOLATILITY.

The market price of the common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of the common stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks set forth in these Risk Factors.

Our common stock has been listed for quotation on the AMEX since May 11, 2004. Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the 12-month period ended January 31, 2006, the closing

price of our common stock has ranged from $1.09 to $1.85. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended January 31, 2006, the average daily trading volume in our common stock was approximately 44,863 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the AMEX. If our common stock were no longer listed on the AMEX, investors might only be able to trade on the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

PENNY STOCK REGULATIONS MAY IMPOSE CERTAIN RESTRICTIONS ON MARKETABILITY OF OUR SECURITIES.

The Commission has adopted regulations which generally define a penny stock to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser s written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the Commission relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer s presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the penny stock rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the Commission, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;

manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;

boiler room practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

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

We are authorized to issue a total of 100,000,000 shares of common stock. As of March 1, 2006, there were 40,667,318 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of January 31, 2006, we had outstanding stock options and warrants to purchase approximately 27.7 million shares of common stock, the exercise price of which range between $0.46 per share to $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

The following table provides an overview of the Company s stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at January 31, 2006	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	80,000		Plan Closed
1997 Stock Option Plan	500,000	100,000		Plan Closed
1998 Stock Option Plan	3,400,000	2,682,000	423,000	
2006 Equity Incentive Plan	6,000,000		6,000,000	
Non-Plan	n/a	5,286,034		

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution. In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

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

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

SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

As permitted by Delaware law, our certificate of incorporation limits the liability of our directors for monetary damages for breach of a director s fiduciary duty except for liability in certain instances. As a result of our charter provision and Delaware law, stockholders may have limited

rights to recover against directors for breach of fiduciary duty. In addition, our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by law.

WE HAVE NO HISTORY OF PAYING DIVIDENDS ON OUR COMMON STOCK.

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We plan to retain any future earnings to finance growth. If we decide to pay dividends to the holders of our common stock, such dividends may not be paid on a timely basis.

PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW COULD DETER A CHANGE OF OUR MANAGEMENT WHICH COULD DISCOURAGE OR DELAY OFFERS TO ACQUIRE US.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board also has the authority to issue preferred stock without further stockholder approval, including large blocks of preferred stock. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of our common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

SALES OF LARGE QUANTITIES OF OUR COMMON STOCK, INCLUDING THOSE SHARES ISSUABLE IN CONNECTION WITH PRIVATE PLACEMENT TRANSACTIONS, COULD REDUCE THE PRICE OF OUR COMMON STOCK.

In 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our Common Stock, and certain warrants to purchase 2,693,209 shares of our Common Stock. The sales of the shares of Common Stock and warrants resulted in gross proceeds to the Company of $7.1 million, prior to offering expenses. The resale of our Common Stock and the exercise of the warrants described immediately above in this risk factor are subject to a currently effective registration statement filed by the Company on Form S-3. There can be no assurance as to the prices at which our Common Stock will trade in the future, although they may continue to fluctuate significantly. Prices for our Common Stock will be determined in the marketplace and may be influenced by many factors, including the following:

- The depth and liquidity of the markets for our Common Stock
- Investor perception of the Company and the industry in which we participate
- General economic and market conditions

Any sales of large quantities of our Common Stock could reduce the price of our Common Stock. The holders of the shares may sell such shares at any price and at any time, as determined by such holders in their sole discretion without limitation. If any such holders sell such shares in large quantities, our Common Stock price may decrease and the public market for our Common Stock may otherwise be adversely affected because of the additional shares available in the market.

THE UNCERTAINTY CREATED BY CURRENT ECONOMIC CONDITIONS AND POSSIBLE TERRORIST ATTACKS AND MILITARY RESPONSES THERETO COULD MATERIALLY ADVERSELY AFFECT OUR ABILITY TO SELL OUR PRODUCTS, AND PROCURE NEEDED FINANCING.

Current conditions in the domestic and global economies continue to present challenges. We expect that the future direction of the overall domestic and global economies will have a significant impact on our overall performance. Fiscal, monetary and regulatory policies worldwide will continue to influence the business climate in which we operate. If these actions are not successful in spurring continued economic growth, we expect that our business will be negatively impacted, as customers will be less likely to buy our products, if and when we commercialize our products. The potential for future terrorist attacks or war as a result thereof has created worldwide uncertainties that make it very difficult to estimate how the world economy will perform going forward.

OUR INABILITY TO MANAGE THE FUTURE GROWTH THAT WE ARE ATTEMPTING TO ACHIEVE COULD SEVERELY HARM OUR BUSINESS.

We believe that, given the right business opportunities, we may expand our operations rapidly and significantly. If rapid growth were to occur, it could place a significant strain on our management, operational and financial resources. To manage any significant growth of our operations, we will be required to undertake the following successfully:

- We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.
- We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel. If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy.

If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

WE MAY BE OBLIGATED, UNDER CERTAIN CIRCUMSTANCES, TO PAY LIQUIDATED DAMAGES TO HOLDERS OF OUR COMMON STOCK.

We have entered into an agreement with the holders of our Common Stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of Common Stock. Such a registration statement was declared effective on July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

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

Our 2006 Annual Meeting of Stockholders was held on January 17, 2006. At that meeting, stockholders elected Thomas E. Bonney, Jan H. Egberts, M.D., William F. Hamilton, Ph.D., J. Jay Lobell, Charles Nemeroff, M.D., Ph.D. and Steven B. Ratoff as Directors of the Company. The terms of these Directors will expire at the 2007 Annual Meeting. In addition, stockholders approved two company proposals. The results of the voting are as follows:

	Votes For	Votes Withheld
Thomas E. Bonney	31,896,074	118,974
Jan H. Egberts, M.D.	31,916,278	98,770
William F. Hamilton, Ph.D.	31,919,623	95,425
J. Jay Lobell	31,967,303	47,745

Charles Nemeroff, M.D., Ph.D.	31,957,178	57,870
Steven B. Ratoff	31,914,378	100,670

	Votes For	Votes Against	Abstain	Broker Non-Vote
Company proposal to approve the 2006 Equity Incentive Plan	17,111,728	2,320,016	94,258	12,489,046

	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, 2006	31,964,133	46,015	4,900	0

ITEM 6. EXHIBITS.

INDEX TO EXHIBITS

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

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
10.1	*1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney	Filed herewith
10.2	*1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton	Filed herewith
10.3	*1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell	Filed herewith
10.4	*1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff	Filed herewith
10.5	*1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Filed herewith
10.6	*Confidential Separation Agreement and General Release between NovaDel Pharma Inc. and Gary Shangold, M.D. dated as of November 29, 2005	Incorporated by reference to Exhibit 10.1 of the Company s Form 8-K, as filed with the SEC on December 2, 2005.
10.7	*Consulting Agreement between NovaDel Pharma Inc. and Gary Shangold, M.D. dated as of November 29, 2005	Incorporated by reference to Exhibit 10.2 of the Company s Form 8-K, as filed with the SEC on December 2, 2005.
10.8	*NovaDel Pharma Inc. 2006 Equity Incentive Plan and Forms of Award Agreements	Incorporated by reference to Exhibit 10.1 of the Company s Form 8-K as filed with the SEC on January 23, 2006.
31.1	Certification Pursuant to Rule 13a-14(a)	Filed herewith
31.2	Certification Pursuant to Rule 13a-14(a)	Filed herewith
32.1	Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished

40

SIGNATURES

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

NovaDel Pharma Inc.

Date: March 15, 2006	By:	/S/ JAN H. EGBERTS Jan H. Egberts, M.D. Chairman of the Board, President and Chief Executive Officer (principal executive officer)
Date: March 15, 2006	By:	/S/ MICHAEL E. SPICER Michael E. Spicer Chief Financial Officer (principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION

Pursuant to Rule 13a-14(a)

I, Jan H. Egberts, M.D., certify that:

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

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

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

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

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

(b) [intentionally omitted]

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

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

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

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

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

Date: March 15, 2006 By: /S/ JAN H. EGBERTS
Jan H. Egberts, M.D.
Chairman of the Board, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

Pursuant to Rule 13a-14(a)

I, Michael E. Spicer, certify that:

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

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

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

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

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

(b) [intentionally omitted]

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

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

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

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

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

Date: March 15, 2006 By: /S/ MICHAEL E. SPICER
Michael E. Spicer
Principal Financial Officer

Exhibit 32.1

CERTIFICATIONS

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

(18 U.S.C. 1350)

In connection with the Quarterly Report of NovaDel Pharma Inc., a Delaware corporation (the Company), on Form 10-Q for the period ended January 31, 2006, as filed with the Securities and Exchange Commission (the Report), Jan H. Egberts, M.D., President and Chief Executive Officer of the Company, and Michael E. Spicer, Principal Financial Officer of the Company, respectively, do each hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. ss. 1350), that to his knowledge:

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

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

Date: March 15, 2006	By:	/s/ Jan H. Egberts Jan H. Egberts, M.D. Chairman of the Board, President and Chief Executive Officer
Date: March 15, 2006	By:	/s/ Michael E. Spicer Michael E. Spicer Chief Financial Officer

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

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

44