NOVADEL PHARMA INC
Form 10-Q
December 14, 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 October 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.

(Exact 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 filer, or a non-accelerated filer. See definition of accelerated filer and large 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 in Rule 12b-2 of the Exchange Act). Yes o No x

As of December 1, 2006, the issuer had 49,366,749 shares of common stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2006

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

This Quarterly 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 Food and Drug Administration, or 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; acceptance for filing by the FDA does not mean that a New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company s internal controls and procedures; and the risks identified under the section entitled Risk Factors included as Item 1A in Part II of this Quarterly Report on Form 10-Q and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVADEL PHARMA INC.

CONDENSED BALANCE SHEETS

AS OF OCTOBER 31, 2006 (UNAUDITED) AND JULY 31, 2006

ASSETS	**October 31, 2006 (unaudited)**	**July 31, 2006**
Current Assets:		
Cash and cash equivalents	$4,089,000	$5,687,000
Short-term investments	4,485,000	4,451,000
Inventories	344,000	585,000
Investment in marketable equity security available for sale	612,000	560,000
Prepaid expenses and other current assets	479,000	491,000
Total Current Assets	10,009,000	11,774,000
Property and equipment, net	2,690,000	2,704,000
Other assets	359,000	344,000
TOTAL ASSETS	$13,058,000	$14,822,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$898,000	$845,000
Accrued expenses and other current liabilities	1,245,000	1,111,000
Current portion of deferred revenue	162,000	162,000
Current portion of capitalized lease obligations	114,000	82,000
Total Current Liabilities	2,419,000	2,200,000
Non-current portion of deferred revenue	2,471,000	2,512,000
Non-current portion of capitalized lease obligations	127,000	65,000
Total Liabilities	5,017,000	4,777,000
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 49,316,749 and 49,123,869 shares at October 31, 2006 and July 31, 2006, respectively	49,000	49,000
Additional paid-in capital	54,870,000	54,417,000
Accumulated deficit	(46,984,000)	(44,475,000)
Accumulated other comprehensive income	112,000	60,000
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders Equity	8,041,000	10,045,000
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$13,058,000	$14,822,000

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED OCTOBER 31, 2006 AND 2005

(UNAUDITED)

	2006	2005
License Fees and Milestone Payments Earned from Related Parties	$ 1,041,000	$ 41,000
Consulting Revenues from Related Parties		109,000
Total Revenues	1,041,000	150,000
Research and Development Expenses	2,164,000	897,000
Consulting, Selling, General and Administrative Expenses	1,492,000	1,871,000
Total Expenses	3,656,000	2,768,000
Loss From Operations	(2,615,000)	(2,618,000)
Interest Income	106,000	43,000
Net Loss	$ (2,509,000)	$ (2,575,000)
Basic and Diluted Loss Per Common Share	$ (.05)	$ (.06)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Share	49,213,000	40,606,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED OCTOBER 31, 2006

(UNAUDITED)

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders Equity
BALANCE, July 31, 2006	49,123,869	$49,000	$54,417,000	$(44,475,000)	$ 60,000	$(6,000)	$10,045,000
Share-based compensation expense			308,000				308,000
Stock issued for options and warrants exercised	192,880		145,000				145,000
Comprehensive income (loss):							
Unrealized gain on investment in marketable equity security					52,000		52,000
Net loss				(2,509,000)			(2,509,000)
Total comprehensive loss							(2,457,000)
BALANCE, October 31, 2006	49,316,749	$49,000	$54,870,000	$(46,984,000)	$ 112,000	$(6,000)	$8,041,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED OCTOBER 31, 2006 AND 2005

(UNAUDITED)

	2006	2005
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(2,509,000)	$ (2,575,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	308,000	350,000
Amortization of discount on short-term investments	(34,000)	
Depreciation and amortization	172,000	103,000
Changes in operating assets and liabilities:		
Accounts receivable from related parties		(15,000)
Inventories	241,000	6,000
Prepaid expenses and other current assets	12,000	(264,000)
Other assets	(15,000)	
Accounts payable	53,000	(560,000)
Accrued expenses and other current liabilities	134,000	(105,000)
Deferred revenue	(41,000)	(41,000)
Net cash used in operating activities	(1,679,000)	(3,101,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(45,000)	(85,000)
Purchases of short-term investments	(200,000)	(1,300,000)
Maturities of short-term investments	200,000	2,448,000
Net cash provided by (used in) investing activities	(45,000)	1,063,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from options and warrants exercised	145,000	18,000
Payments of capitalized lease obligations	(19,000)	
Net cash provided by financing activities	126,000	18,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,598,000)	(2,020,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	5,687,000	4,680,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$4,089,000	$ 2,660,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Equipment acquired under capitalized lease obligation	$113,000	$

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

NOTES TO FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS

NovaDel Pharma Inc. (the Company) is a specialty pharmaceutical company engaged in the development of novel drug delivery systems for prescription and over-the-counter (OTC) drugs. The Company s oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, 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, increasing the benefits of clinically proven compounds, including more rapid absorption into the bloodstream than presently available oral delivery systems.

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

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

On June 28, 2006, the Company s Board of Directors approved a change of the Company s fiscal year end from July 31 to December 31. Accordingly, the new fiscal year will begin on January 1 and end on December 31, beginning January 1, 2007.

NOTE 2 BASIS OF PRESENTATION AND LIQUIDITY

The balance sheet at July 31, 2006, 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-K for the fiscal year ended July 31, 2006, 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-K for the fiscal year ended July 31, 2006.

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The Company has reported a net loss of $2,509,000 and $2,575,000 and negative cash flows from operating activities of $1,679,000 and $3,101,000 for the three months ended October 31, 2006 and 2005, respectively. As of October 31, 2006, the Company had working capital of $7,590,000, cash and cash equivalents of $4,089,000 and short-term investments of $4,485,000. 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, license payments from existing and current and future partners, and royalty payments from sales of approved drugs by partners. The Company can give no assurances that any additional capital that the Company is able to obtain will be sufficient to meet its needs. Although the Company expects to have sufficient cash to fund its operations through July 31, 2007, the Company would have to significantly reduce the pace of its ongoing development of its product candidates unless it can obtain additional working capital. Given the current and desired pace of product development of our product candidates, the Company estimates that it will need to raise additional capital prior to July 31, 2007 in order to fully fund its development activities through July 31, 2007. 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 the Company 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. The Company may not be able to successfully obtain additional financing on terms acceptable to it, or at all. If the Company is unsuccessful at obtaining additional financing as needed, the Company may be required to significantly curtail or cease operations. The Company will need additional financing thereafter until it achieves profitability and positive cash flows, 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.

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. Investments include short-term investments and an investment in marketable common stock received from a licensee. 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 SHARE Loss per common share is computed pursuant to SFAS No. 128, Earnings Per Share. Basic loss per share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of October 31, 2006 and July 31, 2006, there were 30.5 million and 30.7 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 October 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 the 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 of common stock originally reserved for issuance under the 2006 Plan was 6.0 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, and vesting is determined by the Compensation Committee of the Board of Directors. 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. As of October 31, 2006, there were approximately 6.0 million shares available for issuance under the Plans.

The Company adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R) effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R 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 and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

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

Options	Shares (000)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value ($000)
Outstanding at July 31, 2006	8,177	$ 1.65		$
Grants				
Exercises	(162)	.75		
Cancellations	(60)	1.56		
Outstanding at October 31, 2006	7,955	$ 1.67	4.1	$ 569
Exercisable at October 31, 2006	5,212	$ 1.73	3.1	$ 550

In the three months ended October 31, 2006 and 2005, the Company recorded share-based compensation for options using the fair value method required by FAS 123R of approximately $308,000, or $0.01 per share, and $350,000 or $0.01 per share, respectively, which is included in the Company s net loss for each period. As of October 31, 2006, unamortized stock-based compensation expenses of approximately $2.1 million remain to be recognized over a weighted-average period of 1.9 years. There were no options granted during the three months ended October 31, 2006. For grants during the three months ended October 31, 2005, the Company used the following weighted average assumptions in determining fair value under the Black-Scholes model: expected volatility of 64%; dividend yield of 0%; expected term until exercise of 4 years; and risk-free interest rate of 4.1%. 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 addition, under SFAS 123R, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted during the three months ended October 31, 2005 was $0.87. The total intrinsic value of options exercised during the three months ended October 31, 2006 and 2005 was approximately $78,000 and $23,000, respectively.

NOTE 7 - RELATED PARTY TRANSACTIONS AND LICENSE AND DEVELOPMENT AGREEMENTS

License and Development Agreements with Related Parties

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences an exclusive license to develop and market the Company s oral spray version of ondansetron in the U.S. 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 $0.91 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 the three months ended October 31, 2006, the Company received $1,000,000 in milestone payments from Hana Biosciences.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. 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 an equity stake of 529,500 shares of common stock, approximately 15% at the time the shares were issued, in Velcera which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the three months ended October 31, 2006 and 2005, the Company invoiced Velcera approximately $0 and $109,000, respectively, for reimbursable expenses.

In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals 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 license, milestone and other payments, the first $125,000 of which was received in June 2003. In November 2003, the Company received $375,000 from Manhattan Pharmaceuticals 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.

Lindsay A. Rosenwald, M.D., a significant stockholder of the Company, may be deemed to be an affiliate of the Company, Manhattan Pharmaceuticals, Velcera, and Hana Biosciences. 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.

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Other Related Party Transactions

In November 2005, the Company entered into a Confidential Separation Agreement and General Release (the Separation Agreement) and a Consulting Agreement (the Consulting Agreement) with Gary Shangold, M.D. Dr. Shangold is the former President and Chief Executive Officer of the Company. For the three months ended October 31, 2006, pursuant to the Consulting Agreement, the Company paid Dr. Shangold $75,000.

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 U.S. 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.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies the Company s nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX is 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 Biosciences, the Company received $500,000 of common stock of Hana Biosciences (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 October 31, 2006, the Company has classified the shares as available for sale and is recording changes in their value as part of its comprehensive income. Such shares had a market value of $612,000 at October 31, 2006 and, accordingly, the Company has included its $112,000 unrealized gain in accumulated comprehensive income, a separate component of stockholders equity, as of October 31, 2006.

NOTE 9 SUBSEQUENT EVENTS

On December 5, 2006, the Board of Directors (the Board) announced its appointment of Dr. David H. Bergstrom as the Company s Chief Operating Officer, effective December 4, 2006.

The Company and Dr. Bergstrom entered into an Employment Agreement dated as of December 4, 2006 (the Employment Agreement). The Employment Agreement term commenced on December 4, 2006 and will expire on December 3, 2009. In addition, the Company and Dr. Bergstrom entered into an Incentive Stock Option Agreement and a Nonqualified Stock Option Agreement both dated as of December 4, 2006 (the Option Agreements) pursuant to which the Company granted to Dr. Bergstrom options to purchase 900,000 shares of common stock of the Company and a Restricted Stock Award Agreement granting 100,000 shares of restricted stock of the Company. The material terms of the Employment Agreement and Option Agreements and the Restricted Stock Award Agreement are set forth as follows:

Base salary: Pursuant to the Employment Agreement, the Company will pay Dr. Bergstrom a base salary of $300,000 per annum, payable in equal semi-monthly installments.

Bonuses: The Company shall pay Dr. Bergstrom a cash bonus of $100,000 for the period commencing on January 1, 2007 and ending on December 31, 2007, such bonus will be paid in January 2008. In the remaining years of the contract, Dr. Bergstrom shall be eligible to receive a bonus equal to 30% (thirty percent) of his base salary provided, however, that such bonus shall be payable only upon the successful achievement of certain performance milestones related to Dr. Bergstrom s role in the Company, which milestones shall be defined and enumerated by mutual agreement between Dr. Bergstrom and the President and Chief Executive Officer of the Company within the first month of Dr. Bergstrom s term of employment, and again at the same time in each succeeding year of Dr. Bergstrom s term of employment with the Company. The amount of bonus paid to Dr. Bergstrom shall be increased or decreased from time to time at the discretion of the Compensation Committee of the Board.

Stock Options and Restricted Shares: Pursuant to the Employment Agreement, the Company granted Dr. Bergstrom options to purchase 900,000 shares of common stock of the Company, of which 58,479 shares shall be incentive stock options and 841,521 shares shall be nonqualified stock options. The stock options shall vest upon: (i) 12.5% upon acceptance by the Food & Drug Administration (FDA) of our New Drug Application (NDA) submission for our product candidate zolpidem; (ii) 12.5% upon FDA acceptance of a NDA submission for our product candidate sumatriptan; (iii) 12.5% upon Board of Directors approval and successful implementation of portfolio plan for next generation compounds; (iv) 12.5% upon CEO approval and successful implementation of organization plan to address issues in analytical, clinical and regulatory; (v) 15% upon completion of a Board of Directors approved licensing deal for our product candidate zolpidem; (vi) 15% upon completion of a Board of Directors approved licensing deal for our product candidate sumatriptan; and (vii) 20% at the Board of Directors discretion upon completion of an approved licensing deal for our product candidates zolpidem or sumatriptan. Such options will expire on December 3, 2016. The exercise price of each option is $1.71.

On the first day of employment (December 4, 2006), and as additional compensation for the services to be rendered by Dr. Bergstrom pursuant to the Employment Agreement, the Company granted to Dr. Bergstrom 100,000 shares of restricted stock pursuant to the Company s 2006 Equity Incentive Plan. The grant price of said 100,000 Restricted Shares is equal to 100% of the Fair Market Value (trading price) on the first date of employment. Such Restricted Shares grant shall contain restrictions that will vest ratably over a three-year period ending on the third anniversary of the grant so that 33,333 shares of the Company s common stock will vest on the first anniversary of the grant, the second anniversary of the grant, and 33,334 shares of the Company s common stock will vest on the third anniversary of the grant.

Severance: If Dr. Bergstrom s employment is terminated by the Company prior to the expiration of the term of the Employment Agreement or by Dr. Bergstrom for Good Reason (as defined in the Employment Agreement), Dr. Bergstrom will receive certain severance payments and benefits, which vary depending upon the reason for the termination of the Employment Agreement, and which are fully described in the Employment Agreement. In addition, upon the termination, certain options would vest and certain options would be terminated either at the date of termination of the Employment Agreement or at a later date, varying in both cases, depending upon the reason for the termination, all as fully described in the Employment Agreement, the Option Agreements and the Restricted Stock Award Agreement. If Dr. Bergstrom s Employment Agreement were to not be renewed at the expiration of the term thereof by the Company, Dr. Bergstrom will receive certain severance payments and benefits, as fully described in the Employment Agreement, and all of his outstanding options would be deemed to be vested and would expire 90 days after the date of nonrenewal.

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

The following discussion of our financial condition and result of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Quarterly Report. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. Risk Factors of this Quarterly Report, our actual results may differ materially from those anticipated in these forward looking statements.

GENERAL

NovaDel Pharma Inc. is a specialty pharmaceutical company engaged in the development of novel drug delivery systems for prescription and over-the-counter, or OTC, drugs. Our oral spray therapeutics are administered by a novel application drug delivery systems for presently marketed prescription, OTC, and veterinary drugs. This patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, increasing the benefits of clinically proven compounds, including 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 proprietary novel drug delivery system are concentrated on making such system available for drugs that are already available and proven in the marketplace. We believe that our 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) increased bioavailability of a drug by avoiding metabolism by the liver; (iii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iv) improved dosage reliability; (v) allowing medication to be taken without water; (vi) avoiding the need to swallow as is the case with many medications; and (vii) improved patient convenience and compliance. Currently, we have eight patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world.

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 our partnership agreements. Our future growth and profitability will be principally dependent upon our ability to successfully develop our products and to market and distribute the final products either internally or with the assistance of a strategic partner.

On June 28, 2006, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. Accordingly, the new fiscal year will begin on January 1 and end on December 31, beginning January 1, 2007. We have filed our Annual Report on Form 10-K for the period ended July 31, 2006, and we intend to file a transition report on Form 10-K for the period ending December 31, 2006.

Highlights for our fiscal quarter ended October 31, 2006, and additionally through the date of filing for this Quarterly Report on Form 10-Q, include the following product development and business achievements:

Filed a new drug application, or NDA, for Zensana by our partner, Hana Biosciences, Inc., which was accepted for review by the Food and Drug Administration, or FDA.

Added two new central nervous system product candidates to our development pipeline, including tizanidine oral spray potentially for spasticity and ropinirole oral spray potentially for Parkinson s disease.

Appointed Mr. Steven B. Ratoff as Chairman of the Board of Directors effective September 15, 2006 with Dr. Egberts remaining a member of the Board of Directors.

Announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets.

Announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets.

Announced that NitroMist (Nitroglycerin Lingual Aerosol) has been approved by the FDA for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist is NovaDel's first product approval utilizing its proprietary oral spray technology.

Appointed David H. Bergstrom, Ph.D. as Chief Operating Officer.

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Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the FDA or comparable regulatory authorities in foreign countries. 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. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and NDA submission, will take two to three years under the 505(b)(2) NDA process and will require significantly lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates 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, and research and development expenditures may significantly exceed management s expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. 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.

The successful development of our product candidates is highly uncertain. Estimates of the nature, timing and estimated expenses of the efforts necessary to complete the development of, and the period in which material net cash inflows are expected to commence from, any of our product candidates are subject to numerous risks and uncertainties, including:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- results of future clinical trials;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technologies and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote the majority of our research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We have partnered with Par Pharmaceutical, Inc., or Par, who has exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. Subsequent to October 31, 2006, we received a milestone payment from Par for FDA approval. In addition, we will receive royalty payments based upon a percentage of net sales.

Zolpidem Oral Spray. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets. We are currently targeting a NDA submission for our zolpidem product candidate in the first half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

Sumatriptan Oral Spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, or GSK. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets. We are currently targeting a NDA submission for our sumatriptan product candidate in the second half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008; however, we will not be able to launch this product candidate until after the expiration of the relevant Imitrex® patents and extensions thereof in February 2009.

Tizanidine Oral Spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including Multiple Sclerosis, spinal cord injury, stroke and cerebral palsy, and leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We are currently targeting a NDA submission for our tizanidine product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

Ropinirole Oral Spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson s disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson s are 65 years of age or older and it is estimated that approximately 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We are currently targeting a NDA submission for our ropinirole product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

As discussed above, certain of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. As a result, these product candidates are subject to a more difficult, time-consuming and expensive regulatory path in order to commence and complete the preclinical and clinical testing of these product candidates as compared to other product candidates in later stages of development.

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 corporate resources to such activities:

Zensana (Ondansetron Oral Spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Our partner for Zensana , Hana Biosciences, is overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for review by the FDA in August 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive royalty payments based upon a percentage of net sales.

Propofol Oral Spray. Propofol is the active ingredient in Diprivan®, an anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product. Our partner has not provided guidance regarding the clinical and regulatory development plan for this product candidate.

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Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals, Inc., or Velcera. Our partner has not provided guidance regarding the clinical and regulatory development plan for the potential veterinary product candidates.

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 U.S. 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 We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

STOCK-BASED COMPENSATION In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards 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 required 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 began 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.

We have adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R) effective August 1, 2005 and have selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R 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 and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, 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. For the three months ended October 31, 2006 and 2005, we recorded share-based compensation of approximately $308,000 or $0.01 per share and $350,000 or $0.01 per share, respectively. We will continue to incur share-based compensation charges in future periods. As of October 31, 2006, unamortized stock-based compensation expenses of approximately $2.1 million remain to be recognized over a weighted-average period of 1.9 years.

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED OCTOBER 31, 2006 AND 2005

License fees and milestone fees earned from related parties for the three months ended October 31, 2006 were $1,041,000, as compared to $41,000 for the three months ended October 31, 2005. The increase is due to milestone payments received in connection with our license and development agreement for Zensana with Hana Biosciences.

Consulting revenues from related parties for the three months ended October 31, 2006 were $0 as compared to $109,000 for the three months ended October 31, 2005. The decrease is attributable to no revenue from Velcera related to veterinary products during the three months ended October 31, 2006.

Research and development expenses for the three months ended October 31, 2006 were $2,164,000, as compared to $897,000 for the three months ended October 31, 2005. Research and development costs consist primarily of employee salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses by product candidate for the three months ended October 31, 2006 and 2005.

	2006	**2005**
NitroMist	$ 257,000	$ 95,000
Zolpidem	788,000	133,000
Sumatriptan	162,000	66,000
Zensana		62,000
Propofol		
Alprazolam		
Tizanidine	97,000	
Ropinirole	43,000	
Other research and development costs	301,000	131,000
Internal costs	516,000	410,000
Total research and development expenses	$ 2,164,000	$ 897,000

In the preceding table, research and development expenses are set forth in the following categories:

NitroMist , Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. We expect to devote the majority of our research and development resources to our zolpidem and sumatriptan product candidates and expect that costs associated with these product candidates should increase in future periods;

Zensana and Propofol - third-party direct project expenses relating to the development of Zensana . As our partners, Hana Biosciences and Manhattan Pharmaceuticals are overseeing all clinical development and regulatory approval activities for these product candidates, we do not expect to devote a significant amount of resources to these product candidates;

Alprazolam third-party direct project expenses relating to the development of our alprazolam oral spray product candidate. We have determined that, in order to devote sufficient resources to other product candidates, it is appropriate to defer further efforts on alprazolam;

Other research and development costs direct expenses not attributable to a specific product candidate; and

Internal costs costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the three months ended October 31, 2006 increased primarily as a result of the following items:

$162,000 increase primarily related to the establishment of a reserve for a portion of our NitroMist inventory;

$655,000 increase primarily related to product development and clinical trial costs for our zolpidem product candidate;

$96,000 increase primarily related to product development and clinical trial costs for our sumatriptan product candidate; and

$170,000 increase related to other research and development costs primarily as a result of higher lab supplies expense.

Consulting, selling, general and administrative expenses for the three months ended October 31, 2006 were $1,492,000 as compared to $1,871,000 for the three months ended October 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 decrease in consulting, selling, general and administrative costs is primarily related to lower payroll and other personnel related costs during the period.

Total costs and expenses for the three months ended October 31, 2006 were $3,656,000 as compared to $2,768,000 for the three months ended October 31, 2005 primarily due to the net increases in research and development and selling, general and administrative expenses noted above.

The resulting net loss for the three months ended October 31, 2006 was $2,509,000 as compared to $2,575,000 for the three months ended October 31, 2005.

LIQUIDITY AND CAPITAL RESOURCES

From our inception, our principal sources of capital have been consulting revenues, private placements and public offerings of our 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 October 31, 2006 of $46,984,000. We have had negative cash flows from operating activities of $1,679,000 for the three months ended October 31, 2006 as compared to $3,101,000 for the three months ended October 31, 2005. As of October 31, 2006, we had working capital of approximately $7,590,000 as compared to working capital of $9,574,000 as of July 31, 2006, representing a net decrease in working capital of approximately $1,984,000. As explained further below, such decrease is primarily attributable to a net decrease in cash and short-term investments, and a decrease in inventory. In April 2006, we successfully closed a private placement of our common stock and warrants to purchase shares of our common stock, the April 2006 Private Placement. The April 2006 Private Placement involved the sale of 8,092,796 shares of common stock and warrants to purchase 2,427,839 shares of common stock. We received proceeds, net of offering costs, of $10,593,000.

Net cash used in operating activities was approximately $1,679,000 for the three months ended October 31, 2006, as compared to $3,101,000 for the three months ended October 31, 2005. The $1,422,000 decrease in net cash used in operating activities in the three months ended October 31, 2006 compared with the same period in 2005 is due primarily to the following:

- $241,000 decrease in inventory in the three months ended October 31, 2006 primarily related to the establishment of a reserve for a portion of our NitroMist inventory;
- $560,000 decrease in accounts payable in the three months ended October 31, 2005 primarily due to the payment of invoices included in accounts payable at July 31, 2005 related to the manufacturing and process development of NitroMist ; and
- $264,000 increase in prepaid expenses and other current assets in the three months ended October 31, 2005 primarily attributable to the prepayment of a portion of the process validation batches for our nitroglycerin product candidate.

During the three months ended October 31, 2006, $45,000 was used in investing activities, principally due to capital expenditures, and purchases of short-term investments, net of maturities of short-term investments. During the three months ended October 31, 2005, $1,063,000 was provided by investing activities which primarily related to 2,448,000 of maturities of short-term investments and $1,300,000 of purchases of short-term investments.

Cash provided by financing activities was approximately $126,000 in the three months ended October 31, 2006, as compared to $18,000 in the three months ended October 31, 2005. This increase of $108,000 is primarily due to an increase in proceeds received from options and warrants exercised during the period.

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 positive cash flows from operating activities and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from existing and current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Although we expect to have sufficient cash to fund our operations through July 31, 2007, we would have to significantly reduce the pace of our ongoing development of our priority product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our priority product candidates, we estimate that we will need to raise additional capital prior to July 31, 2007 in order to fully fund our development activities through July 31, 2007. 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.

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 our financial condition, results of operations, liquidity or capital resources.

CONTRACTUAL OBLIGATIONS

Our major outstanding contractual obligations relate to our operating leases, employment agreements, consulting agreements, and license agreements with our strategic partners. Since July 31, 2006, there have been no material changes with respect to our contractual obligations as disclosed in our annual report on Form 10-K for the year ended July 31, 2006, other than two new capital lease agreements with aggregate future payments totaling approximately $113,000 and the employment agreement that we entered into with Dr. David H. Bergstrom on December 4, 2006, pursuant to which Dr. Bergstrom was appointed our Chief Operating Officer. See Part II, Item 5 Other Information for more information regarding Dr. Bergstrom s employment agreement.

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, or the Exchange Act, is recorded, processed,

summarized and reported, within the time periods specified in the Rules and Forms of the Securities and Exchange Commission, or the 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 our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of October 31, 2006. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of October 31, 2006, our disclosure controls and procedures were (1) effective in that they were designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our Chief Executive Officer and Chief Financial Officer by others within those entities, as appropriate to allow timely decisions regarding required disclosures, and (2) effective in that they ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

Changes in Internal Controls

During the three months ended October 31, 2006, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 1A. 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 Quarterly Report on Form 10-Q, in our Annual Report on Form 10-K for the fiscal year ended July 31, 2006, and in any documents incorporated in this report by reference.

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 engaged in the development of novel drug delivery systems for prescription and over-the-counter drugs. 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 Food & Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par Pharmaceutical, Inc., or Par, to finalize the commercialization strategy for this product. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of October 31, 2006 of approximately $47.0 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately $2.5 million for the three months ended October 31, 2006, $10.1 million for the fiscal year ended July 31, 2006, $9.5 million for the fiscal year ended July 31, 2005 and $6.3 million for the fiscal year ended July 31, 2004. Additionally, we have reported negative cash flows from operations of approximately $1.7 million for the three months ended October 31, 2006, $8.9 million for the fiscal year ended July 31, 2006, $6.3 million for the fiscal year ended July 31, 2005, and $6.1 million for the fiscal year ended July 31, 2004. 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 product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

The research, development, testing and approval of our product candidates 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 and cash flow, 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 positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from existing, current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. On April 19, 2006, we completed an equity financing in which we received gross proceeds of $11.8 million and approximate net proceeds of $10.6 million. Although we expect to have sufficient cash to fund our operations through July 31, 2007, we would have to significantly reduce the pace of our ongoing development of our product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our product candidates, we estimate that we will need to raise additional capital prior to July 31, 2007 in order to fully fund our development activities through July 31, 2007. This could include the securing of funds through new strategic 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 existing 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 our 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. At our Annual Meeting in January 2007, our stockholders will be asked to approve an amendment to our Certificate of Incorporation to increase the number of authorized shares of our Common Stock. Our current Certificate of Incorporation authorizes the issuance of a total of 101,000,000 shares, of which 100,000,000 shares are Common Stock and 1,000,000 shares are preferred stock. The Board has proposed an amendment to our Certificate of Incorporation to increase the total number of authorized shares from 101,000,000 to 201,000,000; if approved, the authorized shares of Common Stock will increase from 100,000,000 to 200,000,000; and the authorized shares of preferred stock will remain at 1,000,000. The stockholders are being asked to approve the proposed amendment in accordance with Delaware law. See Risk Factors Additional Authorized Shares of our Common Stock and Preferred Stock Available for Issuance May Adversely Affect the Market for a description of certain rights of Paramount BioCapital Inc., or Paramount, 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 could potentially enhance speed of onset of therapeutic effect, could potentially 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. Our most recent new product candidates, tizanidine and ropinirole, are focused on the neurology segment, where we believe that the benefits of our proprietary drug delivery technology may apply to a number of different pharmaceutical products.

On November 3, 2006, we announced that the FDA has approved our NitroMist (nitroglycerin lingual aerosol) for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist is NovaDel's first approval that utilizes its proprietary oral spray technology.

Our partner in North America, Hana Biosciences, Inc., or Hana Biosciences, for our ondansetron oral spray product candidate is overseeing all clinical development and regulatory approval activities. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for filing by the FDA in August 2006. Hana Biosciences expects final approval from the FDA and commercial launch in calendar 2007.

We completed pilot pharmacokinetic studies of our certain product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, propofol and zolpidem. In addition, in September and October 2006, we completed a pharmacokinetic study of our improved oral spray formulation of sumatriptan and zolpidem, respectively. 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 desired therapeutic 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, an alprazolam 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 these product candidates has been put on hold.

We have also commenced formulation work on two new product candidates, tizanidine oral spray and ropinirole oral spray.

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 us, is the Chairman and sole shareholder of 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. As of December 1, 2006, Dr. Rosenwald beneficially owns approximately 17% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). 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 our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. 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 American Stock Exchange, or AMEX, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with private placements. Refer to Note 7 of the Condensed Financial Statements included in this Quarterly Report Related Party Transactions and License and Development Agreements for additional information. 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 or 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 to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. 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 product candidates 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 Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates 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.

SOME OF OUR PRODUCT CANDIDATES ARE IN EARLY STAGES OF CLINICAL DEVELOPMENT AND SOME ARE IN PRECLINICAL TESTING, WHICH MAY AFFECT OUR ABILITY OR THE TIME WE REQUIRE TO OBTAIN NECESSARY REGULATORY APPROVALS.

Some of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience delays with our preclinical and clinical testing, and a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates as compared to others in our pipeline at later stages of development. These delays may negatively affect our business and operations.

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of calendar 2006 or the first half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates 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 product candidates 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 product candidates 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 product candidates must be obtained before the product candidates will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps the first half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. 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 product candidates or develop such product candidates on a timely basis. Further, such product candidates 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 product candidates, 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 product candidates. 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, Manhattan Pharmaceuticals, Velcera and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our product candidates. 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 possibly 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, or 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 product candidates. 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 product candidates are presently available from numerous suppliers located in the U.S., 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 product candidates, 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 USA, Ltd., which 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 USA, Ltd. 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.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 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 of 2002, 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 of 2002 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 of 2002. 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 price of our common stock. As of the date of the filing of this Quarterly Report on Form 10-Q, we will have to comply with Section 404 of the Sarbanes-Oxley Act of 2002 as of December 31, 2007.

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, or SEC, and American Stock Exchange, or 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, larger and/or better capitalized pharmaceutical companies with currently marketed 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 product candidates. 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 Biotechnology Corporation is listed as the assignee on 15 U.S. 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 UK, 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. Sosei Co. Ltd. is 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 product candidates, 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 product candidates, 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 U.S. 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, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. 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. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under 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 filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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 for an NDA 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.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote the majority of our internal research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We have partnered with Par, who has exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. Subsequent to October 31, 2006, we received a milestone payment from Par for FDA approval. In addition, we will receive royalty payments based upon a percentage of net sales.

Zolpidem oral spray. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets. We are currently targeting a NDA submission for our zolpidem product candidate in the first half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

Sumatriptan oral spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, GSK. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets. We are currently targeting a NDA submission for our sumatriptan product candidate in the second half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008; however, we will not be able to launch this product candidate until after the expiration of the relevant Imitrex® patents and extensions thereof in February 2009.

Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including Multiple Sclerosis, spinal cord injury, stroke and cerebral palsy, and leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We are currently targeting a NDA submission for our tizanidine product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

Ropinirole oral spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that approximately 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We are currently targeting a NDA submission for our ropinirole product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

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:

Zensana (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Our partner for Zensana , Hana Biosciences, is overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for review by the FDA in August 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive royalty payments based upon a percentage of net sales.

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Propofol oral spray. Propofol is the active ingredient in Diprivan®, an anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product. Our partner has not provided guidance regarding the clinical and regulatory development plan for this product candidate.

Our veterinary initiatives are being carried out largely by our partner, Velcera. Our partner has not provided guidance regarding the clinical and regulatory development plan for the potential veterinary product candidates.

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 U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist , the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. 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 U.S. 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 INCLUDES ENTERING INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES FOR CERTAIN OF OUR PRODUCT CANDIDATES 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 certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes 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 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 pursuant to which Par has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the U.S. and Canada; and a license agreement with Hana Biosciences for the marketing rights in the U.S. 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 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 such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, 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 U.S. 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 U.S. Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the U.S. 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.

Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits an applicant to rely upon the FDA s findings of safety and effectiveness for an approved product. The FDA may also require companies to perform one or more additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or a new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA s findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed (paragraph I certification); (2) the listed patent has expired (paragraph II certification); (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product (paragraph IV certification). If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, and once any pediatric exclusivity expires. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner once the NDA has been accepted for filing by the FDA. The NDA holder and patent owner may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in an infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the NDA holder or patent owner does not file a patent infringement lawsuit within the required 45-day period, the applicant s NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Our partner, Hana Biosciences, submitted a Section 505(b)(2) NDA for Zensana in the second quarter of 2006. The safety and efficacy of the drug will be based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by two unexpired patents, one of which expired in June 2006, and that is subject to a period of pediatric exclusivity expiring in December 2006. The second patent is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Hana Biosciences Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the first patent will expire in December 2006, and a paragraph IV certification to the second patent. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us and/or Hana Biosciences for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences has announced that it has not received any objections related to these patent certifications.

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.

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 U.S. and foreign patent applications with respect to the products and technologies under our development, and the U.S. 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. Currently, we have eight patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the U.S. 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 U.S. 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 product candidates and processes in the U.S. 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 U.S. Patent and Trademark Office keeps U.S. 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 could 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 could 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, or Board, announced that they would not be renewing the employment contract of Dr. Gary A. 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 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 October 20, 2005, we announced that Dr. Henry Kwan would no longer serve as Head of Pharmaceutical Sciences.

On November 22, 2005, we announced that Board 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 our 2006 annual meeting of stockholders. Mr. Savage served as a director since 2004 and as our non-executive Chairman of the Board since September 2, 2005.

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

On December 15, 2005, we announced the election of Mr. J. Jay Lobell as a member of our Board effective December 14, 2005. Mr. Lobell was appointed as a result of Dr. Rosenwald s right to designate a director nominee for our Board. Although Mr. Lobell is a designee of Dr. Rosenwald s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. As of September 15, 2006, Mr. Lobell has been deemed independent by our Board of Directors in accordance with the rules of AMEX.

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 our 2006 annual stockholders meeting. Dr. Kessel served as a director since March 2003.

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

On April 24, 2006, Ms. Jean Frydman ceased to serve as Vice President, General Counsel and Corporate Secretary.

On September 15, 2006, our Board of Directors appointed Steven B. Ratoff as Chairman of the Board, with Dr. Egberts remaining a member of the Board of Directors.

On December 4, 2006, our Board of Directors appointed David H. Bergstrom, Ph.D. as Chief Operating Officer.

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 35% 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. Dr. Rosenwald has the ability to designate an individual to serve on our Board and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. 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 has been deemed to be an independent director by our Board of Directors on September 15, 2006.

Such positions may discourage or prevent any proposed takeover of us, 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 our 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 our 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 U.S. 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 and other reports, including this Report and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the AMEX since May 11, 2004 under the symbol NVD . 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 October 31, 2006, the closing price of our common stock has ranged from $1.11 to $1.90. 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 October 31, 2006, the average daily trading volume in our common stock was approximately 68,000 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.

BECAUSE THE AVERAGE DAILY TRADING VOLUME OF OUR COMMON STOCK IS LOW, THE ABILITY TO SELL OUR SHARES IN THE SECONDARY TRADING MARKET MAY BE LIMITED.

Because the average daily trading volume of our common stock on the AMEX is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors ability to sell shares in the secondary trading market.

WE LIKELY WILL ISSUE ADDITIONAL EQUITY SECURITIES, WHICH WILL DILUTE CURRENT STOCKHOLDERS SHARE OWNERSHIP.

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute current stockholders share ownership.

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

The SEC 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 SEC 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 SEC, 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 and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. At our Annual Meeting in January 2007, our stockholders will be asked to approve an amendment to our Certificate of Incorporation to increase the number of authorized shares of our common stock. Our current Certificate of Incorporation authorizes the issuance of a total of 101,000,000 shares. The Board has proposed an amendment to our Certificate of Incorporation to increase the total number of authorized shares from 101,000,000 to 201,000,000; if approved, the authorized shares of common stock will increase from 100,000,000 to 200,000,000 and the authorized shares of preferred stock will remain at 1,000,000. The stockholders are being asked to approve the proposed amendment in accordance with Delaware law. As of December 1, 2006, there were 49,366,749 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 December 1, 2006, we had outstanding stock options and warrants to purchase approximately 30.4 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 our stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at December 1, 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	2,624,000	471,000	
2006 Equity Incentive Plan	6,000,000	450,000	5,550,000	
Non-Plan	n/a	4,636,000		

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 herein. 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. 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 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 of 1933, as amended, 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.

On July 20, 2006, we filed a shelf registration statement on Form S-3 registering for sale by us of up to 14,000,000 shares of our common stock. Such shelf registration statement was declared effective by the SEC on August 2, 2006. We may offer and sell such shares from time to time, in one or more offerings in amounts and at prices, and on terms determined at the time of the offering. Such offerings of our common stock may be made through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation at the time of the offering. As of the filing date of this Quarterly Report, this Registration Statement is no longer effective.

In April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,168 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $11.8 million, prior to offering expenses.

In May 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 2,693,210 shares of our common stock. The sales of the shares of common stock and warrants resulted in gross proceeds to us of $7.1 million, prior to offering expenses.

The offering of, and/or resale of our common stock and the exercise of the warrants described immediately above in this risk factor are subject to currently effective registration statements filed by us on Forms 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 us and the industry in which we participate; and
- 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.

As of December 1, 2006, we have 49,366,749 shares of common stock issued and outstanding and 30.4 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 100,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions. At our Annual Meeting in January 2007, our stockholders will be asked to approve an amendment to our Certificate of Incorporation to increase the number of authorized shares of our common stock. Our current Certificate of Incorporation authorizes the issuance of a total of 101,000,000 shares, of which 100,000,000 shares are common stock and 1,000,000 shares are preferred stock. The Board has proposed an amendment to our Certificate of Incorporation to increase the total number of authorized shares from 101,000,000 to 201,000,000; if approved, the authorized shares of the common stock will increase from 100,000,000 to 200,000,000; and the authorized shares of preferred stock will remain at 1,000,000. The stockholders are being asked to approve the proposed amendment in accordance with Delaware law.

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 agreements 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 registration statements were declared effective on July 28, 2005 and May 30, 2006 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 5. OTHER INFORMATION

On December 1, 2006, we were notified that on October 10, 2006, we were issued a patent by the Canadian Patent Office covering the use of multiple classes of drugs in oral sprays. Canadian Patent No. 2,252,038 covers the use of a pharmacologically active compound selected from the group consisting of non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepines and anti-depressants for the preparation of a buccal aerosol pump spray composition that would be absorbed through the oral mucosa in a polar solvent. This patent complements a Canadian patent issued to us in March of 2006 that covered the use of a non-polar solvent.

On December 5, 2006, the Board of Directors, or the Board, announced its appointment of Dr. David H. Bergstrom as our Chief Operating Officer, effective December 4, 2006. There was no arrangement or understanding between Dr. Bergstrom and any other persons pursuant to which Dr. Bergstrom was appointed Chief Operating Officer.

We entered into an Employment Agreement with Dr. Bergstrom dated as of December 4, 2006, the Employment Agreement. The Employment Agreement term commenced on December 4, 2006 and will expire on December 3, 2009. In addition, we entered into an Incentive Stock Option Agreement and a Nonqualified Stock Option Agreement with Dr. Bergstrom both dated as of December 4, 2006, the Option Agreements, pursuant to which we granted to Dr. Bergstrom options to purchase 900,000 shares of common stock and a Restricted Stock Award Agreement granting 100,000 shares of our restricted stock. The material terms of the Employment Agreement and Option Agreements and the Restricted Stock Award Agreement are set forth as follows:

Base salary: Pursuant to the Employment Agreement, we will pay Dr. Bergstrom a base salary of $300,000 per annum, payable in equal semi-monthly installments.

Bonuses: We shall pay Dr. Bergstrom a cash bonus of $100,000 for the period commencing on January 1, 2007 and ending on December 31, 2007, such bonus will be paid in January 2008. In the remaining years of the contract, Dr. Bergstrom shall be eligible to receive a bonus equal to 30% (thirty percent) of his base salary provided, however, that such bonus shall be payable only upon the successful achievement of certain performance milestones related to Dr. Bergstrom s role with us, which milestones shall be defined and enumerated by mutual agreement between Dr. Bergstrom and our President and Chief Executive Officer within the first month of Dr. Bergstrom s term of employment, and again at the same time in each succeeding year of Dr. Bergstrom s term of employment with us. The amount of bonus paid to Dr. Bergstrom shall be increased or decreased from time to time at the discretion of the Compensation Committee of the Board.

Stock Options and Restricted Shares: Pursuant to the Employment Agreement, we granted Dr. Bergstrom options to purchase 900,000 shares of our common stock, of which 58,479 shares shall be incentive stock options and 841,521 shares shall be nonqualified stock options. The stock options shall vest upon: (i) 12.5% upon acceptance by the FDA of our NDA submission for our product candidate zolpidem; (ii) 12.5% upon FDA acceptance of a NDA submission for our product candidate sumatriptan; (iii) 12.5% upon Board of

Directors approval and successful implementation of portfolio plan for next generation compounds; (iv) 12.5% upon CEO approval and successful implementation of organization plan to address issues in analytical, clinical and regulatory; (v) 15% upon completion of a Board approved licensing deal for our product candidate zolpidem; (vi) 15% upon completion of a Board approved licensing deal for our product candidate sumatriptan; and (vii) 20% at the Board s discretion upon completion of an approved licensing deal for our product candidates zolpidem or sumatriptan. Such options will expire on December 3, 2016. The exercise price of each option is $1.71.

On the first day of employment (December 4, 2006), and as additional compensation for the services to be rendered by Dr. Bergstrom pursuant to the Employment Agreement, we granted to Dr. Bergstrom 100,000 shares of restricted stock pursuant to our 2006 Equity Incentive Plan. The grant price of said 100,000 Restricted Shares is equal to 100% of the Fair Market Value (trading price) on the first date of employment. Such Restricted Shares grant shall contain restrictions that will vest ratably over a three-year period ending on the third anniversary of the grant so that 33,333 shares of our common stock will vest on the first anniversary of the grant, the second anniversary of the grant, and 33,334 shares of our common stock will vest on the third anniversary of the grant.

Severance: If Dr. Bergstrom s employment is terminated by us prior to the expiration of the term of the Employment Agreement or by Dr. Bergstrom for Good Reason (as defined in the Employment Agreement), Dr. Bergstrom will receive certain severance payments and benefits, which vary depending upon the reason for the termination of the Employment Agreement, and which are fully described in the Employment Agreement. In addition, upon the termination, certain options would vest and certain options would be terminated either at the date of termination of the Employment Agreement or at a later date, varying in both cases, depending upon the reason for the termination, all as fully described in the Employment Agreement, the Option Agreements and the Restricted Stock Award Agreement. If Dr. Bergstrom s Employment Agreement were to not be renewed at the expiration of the term thereof by the Company, Dr. Bergstrom will receive certain severance payments and benefits, as fully described in the Employment Agreement, and all of his outstanding options would be deemed to be vested and would expire 90 days after the date of nonrenewal.

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*	Employment Agreement by and between the Company and David H. Bergstrom, Ph.D., dated December 4, 2006.	Incorporated by reference to Exhibit 10.1 of the Company s Form 8-K, as filed with the SEC on December 8, 2006
10.2*	Incentive Stock Option Agreement by and between the Company and David H. Bergstrom, Ph.D., dated December 4, 2006.	Incorporated by reference to Exhibit 10.2 of the Company s Form 8-K, as filed with the SEC on December 8, 2006
10.3*	Nonqualified Stock Option Agreement by and between the Company and David H. Bergstrom, Ph.D., dated December 4, 2006.	Incorporated by reference to Exhibit 10.3 of the Company s Form 8-K, as filed with the SEC on December 8, 2006
10.4*	Restricted Stock Award granted to David H. Bergstrom, Ph.D., dated December 4, 2006.	Incorporated by reference to Exhibit 10.4 of the Company s Form 8-K, as filed with the SEC on December 8, 2006
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350, Section 1330 as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: December 14, 2006	By:	/S/JAN H. EGBERTS Jan H. Egberts, M.D. President and Chief Executive Officer (principal executive officer)
Date: December 14, 2006	By:	/S/MICHAEL E. SPICER Michael E. Spicer Chief Financial Officer (principal financial and accounting officer)