NOVADEL PHARMA INC
Form 10-Q
November 12, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

or

oTRANSITION 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 (State or other jurisdiction of incorporation or organization)	**22-2407152** (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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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 November 1, 2008, the issuer had 60,692,260 shares of common stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008

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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 on Form 10-Q 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 U.S. 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 the 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 SEPTEMBER 30, 2008 (UNAUDITED) AND DECEMBER 31, 2007

ASSETS	**September 30, 2008**	**December 31, 2007**
	(unaudited)	**(Note 2)**
Current Assets:		
Cash and cash equivalents	$2,409,000	$6,384,000
Assets held-for-sale	178,000	492,000
Deferred financing costs, net of accumulated amortization of $134,000	61,000	—
Prepaid expenses and other current assets	1,019,000	1,146,000
Total Current Assets	3,667,000	8,022,000
Property and equipment, net	1,575,000	1,972,000
Other assets	296,000	369,000
TOTAL ASSETS	$5,538,000	$10,363,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Secured convertible notes payable, net of unamortized debt discount of $376,000	$1,099,000	$—
Accounts payable	451,000	1,632,000
Accrued expenses and other current liabilities	698,000	2,267,000
Current portion of deferred revenue	266,000	148,000
Current portion of capitalized lease obligations	133,000	164,000
Total Current Liabilities	2,647,000	4,211,000
Non-current portion of deferred revenue	4,534,000	1,830,000
Non-current portion of capitalized lease obligations	50,000	148,000
Total Liabilities	7,231,000	6,189,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		
	60,000	59,000

Authorized 200,000,000, issued 60,692,260 and 59,592,260 shares at September 30, 2008 and December 31, 2007, respectively		
Additional paid-in capital	71,173,000	69,364,000
Accumulated deficit	(72,920,000)	(65,243,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders' Equity	(1,693,000)	4,174,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$5,538,000	$10,363,000

See accompanying notes to unaudited condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2008 AND SEPTEMBER 30, 2007

(UNAUDITED)

	Three Months Ended		**Nine Months Ended**	
	September 30, 2008	**September 30, 2007**	**September 30, 2008**	**September 30, 2007**
License Fees and Milestone Fees Earned	$104,000	$ 206,000	$258,000	$411,000
Research and Development Expenses	705,000	2,086,000	3,151,000	8,508,000
Consulting, Selling, General and Administrative Expenses	1,164,000	951,000	3,473,000	5,539,000
Loss on Assets-Held-for-Sale	9,000	—	351,000	—
Total Expenses	1,878,000	3,037,000	6,975,000	14,047,000
Loss From Operations	(1,774,000)	(2,831,000)	(6,717,000)	(13,636,000)
Other Income (Loss)	—	294,000	—	(66,000)
Interest Expense	(750,000)	—	(1,044,000)	—
Interest Income	21,000	127,000	84,000	544,000
Net Loss	$(2,503,000)	$ (2,410,000)	$(7,677,000)	$(13,158,000)
Basic and Diluted Loss Per Common Share	$(0.04)	$ (0.04)	$(0.13)	$(0.22)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	59,592,000	59,591,000	59,592,000	59,465,000

See accompanying notes to unaudited condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008

(UNAUDITED)

	Common Stock					
	Shares	**Amount**	**Additional Paid-In Capital**	**Accumulated Deficit**	**Treasury Stock**	**Total Stockholders' Equity**
BALANCE, December 31, 2007	59,592,260	$ 59,000	$ 69,364,000	$ (65,243,000)	$ (6,000)	$ 4,174,000
Share-based compensation expense	—	—	600,000	—	—	600,000
Restricted stock issued	1,100,000	1,000	(1,000)	—	—	—
Warrants issued to investors and beneficial conversion feature embedded in convertible notes	—	—	1,210,000		—	1,210,000
Net loss	—	—	—	(7,677,000)	—	(7,677,000)
BALANCE, September 30, 2008	60,692,260	$ 60,000	$ 71,173,000	$ (72,920,000)	$ (6,000)	$ (1,693,000)

See accompanying notes to unaudited condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND SEPTEMBER 30, 2007

(UNAUDITED)

	Nine Months Ended September 30, 2008	September 30, 2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,677,000)	$ (13,158,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	600,000	622,000
Amortization of discount on short-term investments	—	(100,000)
Depreciation and amortization	397,000	522,000
Amortization of debt discount and deferred financing fees	968,000	—
Loss on assets held-for-sale	351,000	—
Loss from return of investment in marketable equity security available for sale to issuer	—	140,000
Other than temporary impairment of investment in marketable equity security available-for-sale	—	360,000
Changes in operating assets and liabilities:		
Inventory	—	(78,000)
Prepaid expenses and other current assets	127,000	(378,000)
Other assets	36,000	(10,000)
Accounts payable	(1,181,000)	641,000
Accrued expenses and other current liabilities	(1,569,000)	24,000
Deferred revenue	2,822,000	(636,000)
Net cash used in operating activities	(5,126,000)	(12,051,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	—	(179,000)
Purchases of short-term investments	—	(9,737,000)
Maturities of short-term investments	—	10,155,000
Net cash provided by investing activities	—	239,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock through private placements	—	1,395,000
Proceeds from issuance of convertible notes	1,475,000	—
Deferred financing costs	(195,000)	—
Proceeds from options and warrants exercised	—	200,000
Payments of capitalized lease obligations	(129,000)	(117,000)
Net cash provided by financing activities	1,151,000	1,478,000
DECREASE IN CASH AND CASH EQUIVALENTS	(3,975,000)	(10,334,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	6,384,000	16,586,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 2,409,000	$ 6,252,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Equipment acquired under capitalized lease obligation	$ —	$ 228,000
Warrants – discount and beneficial conversion feature	$ 1,210,000	$ —

See accompanying notes to unaudited condensed financial statements.

NOVADEL PHARMA INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS

NovaDel Pharma Inc. (the "Company") is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed drugs. The Company's proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and adherence. The Company's oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products, with the most advanced oral spray candidates targeting angina, nausea, insomnia, migraine headaches and disorders of the central nervous system.

NOTE 2 – BASIS OF PRESENTATION AND LIQUIDITY

The balance sheet at December 31, 2007 has been derived from the audited balance sheet contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as amended, 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. However, 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 year ended December 31, 2007, as amended.

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.

The Company has reported a net loss of $7,677,000 and $13,158,000 and negative cash flows from operating activities of $5,126,000 and $12,051,000 for the nine months ended September 30, 2008 and September 30, 2007, respectively. As of September 30, 2008, the Company had working capital of $1,020,000, and cash and cash equivalents of $2,409,000. Until and unless the Company's operations generate significant revenues and cash flow, 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 positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs, or on terms favorable to it. During the fourth quarter 2007, the Company significantly reduced clinical development activities on its product candidate pipeline, as it did not believe that it had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, the Company requires capital to sustain its existing organization until such time as clinical activities can be resumed. The Company received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing, and on April 17, 2009, with respect to the Subsequent

Closing, the noteholders may either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of the assets of the Company, other than certain excluded assets. During the second quarter of 2008, the Company also entered into a European partnership for its ondansetron oral spray with BioAlliance Pharma S.A. (“BioAlliance”), as a result of which the Company received an immediate non-refundable license fee of $3,000,000.

Given the current level of spending, and assuming that ProQuest does not convert its notes into common stock, but demands payment under the notes issued in the Initial Closing and the Subsequent Closing, the Company estimates that it will have sufficient cash on hand to fund operations through December 2008. In the event, however, that ProQuest converts its notes into shares of common stock, then the Company estimates that it will have sufficient cash to fund operations through the second quarter of 2009.

The Company may also determine that it is appropriate to increase development activities on its product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations through the second quarter of 2009. The Company may choose to raise additional capital before December 31, 2008, or in early 2009, to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities.

Given the recent downturn in the economy, there can be no assurance that public or private capital will be available to the Company on favorable terms, or at all. There are a number of risks and uncertainties related to its attempt to complete a financing or strategic partnering arrangement that are outside its control. The Company may not be able to obtain additional financing on terms acceptable to it, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. The Company will need additional financing thereafter until it achieves profitability, if ever.

The Company's audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that the Company will continue its operations as a going concern. The Company was incorporated in 1982, and has a history of losses. As a result, the Company's independent registered public accounting firm in their audit report has expressed substantial doubt about the Company's ability to continue as a going concern. The Company believes that the cash inflows that have been generated from the convertible note financing, along with the $3,000,000 non-refundable license fee received from BioAlliance and any additional potential cash inflows that may be received during the remainder of 2008 and early 2009, will improve its ability to continue its operations as a going concern. Continued operations are dependent on the Company's ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. The Company's financial statements do not include any adjustments that may result from the outcome of this uncertainty.

On May 14, 2008, the Company received notice from the NYSE Alternext US LLC (formally known as the American Stock Exchange (the "NYSE Alternext")) indicating that the Company is not in compliance with certain of the NYSE Alternext continued listing standards. Specifically, the NYSE Alternext has notified the Company that it is not in compliance with Section 1003(a)(iii) of the NYSE Alternext Company Guide with stockholders' equity of less than $6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years, and Section 1003(a)(iv) of the NYSE Alternext Company Guide in that it has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Alternext, as to whether such company will be able to continue operations and/or meet its obligations as they mature.

In order for the Company to maintain its NYSE Alternext listing, the Company was required to submit a plan by June 13, 2008, advising the NYSE Alternext of the actions it has taken, or will take, that will bring it into compliance with Section 1003(a)(iv) by November 14, 2008, and Section 1003(a)(iii) by November 16, 2009. The Company informed the NYSE Alternext that it intended to submit such a plan, and did so on June 12, 2008.

On July 30, 2008, NYSE Alternext notified the Company that the NYSE Alternext had completed its review of the Company's proposed plan of compliance and supporting documentation and has determined that, although the Company is not in compliance with the continued listing standards of the NYSE Alternext, the Company has made a reasonable demonstration of its ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Alternext is continuing the Company's listing pursuant to an extension, subject to certain conditions.

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In addition, as of September 30, 2008, the Company is no longer in compliance with Section 1003(a)(ii) of the NYSE Alternext Company Guide with stockholders' equity of less than $4,000,000 and losses from continuing operations and net losses in three of its four most recent fiscal years; and Section 1003(a)(i) of the NYSE Alternext Company Guide with stockholders' equity of less than $2,000,000 and losses from continuing operations and net losses in two of its three most recent fiscal years. However, as previously noted, the plan submitted by the Company to the NYSE Alternext on June 13, 2008 reasonably demonstrates the Company's ability to attain a stockholders' equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

The Company will be subject to periodic review by the NYSE Alternext during the plan periods and must continue to provide the NYSE Alternext with updates in conjunction with the initiatives of the plan as appropriate or upon request, and failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in the Company being delisted from the NYSE Alternext.

There can be no assurance that the Company will be able to make progress consistent with the Company's plan to regain compliance with NYSE Alternext's continued listing standards in a timely manner, if at all. The Company may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE Alternext Company Guide.

NOTE 3 – CONVERTIBLE NOTES

On May 6, 2008, the Company entered into a binding Securities Purchase Agreement by and among ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., referred to herein as the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company and the Purchasers, to sell up to $4,000,000 of secured convertible promissory notes, referred to herein as the convertible notes, and accompanying warrants to such Purchasers, referred to herein as the 2008 Financing. Mr. Steven Ratoff, the Company's Chairman, Interim President and Chief Executive Officer, is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments.

On May 30, 2008, the Company closed the initial portion of the transaction, referred to herein as the Initial Closing, for $1,475,000, representing no more than 5,000,000 shares of the common stock underlying the convertible notes, upon receipt of approval from the NYSE Alternext, and satisfaction of customary closing conditions. The 5,000,000 shares, along with the prior securities owned by the Purchasers, represented 19.8% of the Company's outstanding common stock upon execution of the Securities Purchase Agreement. At its Annual Stockholders' Meeting on September 8, 2008, the Company sought and received stockholder approval to fund additional amounts such that the total commitment, inclusive of the amount at the Initial Closing, equals up to $4,000,000, referred to herein as the Subsequent Closing and together with the Initial Closing, the Closings. On October 17, 2008, the Company closed the Subsequent Closing, for gross proceeds of $2,525,000.

In the Initial Closing, the Company issued the convertible notes, which convert into its common stock at a fixed price of $0.295 per share subject to certain adjustments, and five-year warrants to purchase 3,000,000 shares of its common stock, with an exercise price of $0.369 per share. The maturity date of the convertible notes issued in the Initial Closing is November 30, 2008.

In the Subsequent Closing, the Company issued the convertible notes, which convert into 10,744,681 shares of its common stock at a fixed price of $0.235 per share subject to certain adjustments, and five-year warrants to purchase 6,446,809 shares of its common stock, with an exercise price of $0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing is April 17, 2009.

The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10%. All unpaid principal, together with any accrued but unpaid interest and other amounts payable under the convertible notes, shall be due and payable upon the earliest to occur of (i) when such amounts are declared due and payable by the Purchasers on or after the date that is 180 days after the date of issuance; or (ii) upon the occurrence of any change of control event. At the option of the Purchasers, interest may be paid in cash or in common stock of the Company. If the Company pays interest in common stock, the stock will be valued at the related conversion price for such convertible note. Therefore, on November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes issued at maturity.

At its option, the Company can redeem without penalty or premium a portion of, or all of, the principal owed under the convertible notes by providing the Purchasers with at least 5 days' written notice; provided that the Purchasers shall retain conversion rights in respect of the convertible notes for such period of 5 days after the Company has given such notice. Each prepayment shall be accompanied by the payment of accrued and unpaid interest on the amount being prepaid, through the date of the prepayment.

The Company's obligations under the convertible notes are secured by all of its assets and intellectual property, with the exception of certain excluded assets, as evidenced by the Security and Pledge Agreement, executed on May 6, 2008. Excluded assets of the Company are (i) those assets that are the subject of its existing capital leases (approximately $491,000 in net book value of fixed assets as of September 30, 2008, on which $183,000 of capital lease obligations exist at September 30, 2008); (ii) the assets marked as "Assets held for sale" on its balance sheets as of December 31, 2007 and September 30, 2008, which represented assets associated with our NitroMist™ product which is currently being targeted for sale, the amount for which was $178,000 as of September 30, 2008; and (iii) the assets marked as "Other Assets" on its balance sheets as of December 31, 2007 and September 30, 2008, which represented restricted cash held as security for its letters of credit and leased assets, the amount for which was $296,000 as of September 30, 2008.

The conversion rate of each convertible note and the exercise price of the warrants are subject to adjustment for certain events, including dividends, stock splits and combinations.

The Company filed an initial registration statement with the SEC to register the resale of common stock issuable in connection with the Initial Closing (excluding interest shares), referred to herein as the initial registrable shares, on June 26, 2008, which registration statement became effective as of July 16, 2008. These registration rights will cease once the initial registrable shares are eligible for sale by the Purchasers without restriction under Rule 144. Upon certain events, the Company has agreed to pay as partial liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the Purchasers for any convertible notes then held by the Purchasers, but these payments may not exceed 10% of the aggregate purchase price paid by the Purchasers. The Company intends to file a registration statement with the SEC to register the resale of common stock issuable in connection with the Subsequent Closing (including interest shares from the Initial Closing) as soon as possible.

The Purchasers represented that they are "accredited investors" and agreed that the securities issued in the 2008 Financing bear a restrictive legend against resale without registration under the Securities Act. The convertible notes and warrants were sold pursuant to the exemption from registration afforded by Section 4(2) of the Securities Act and Regulation D thereunder.

Under EITF 00-27, "Application of Issue No. 98-5 to Certain Convertible Instrument," the value of the warrants issued to the investors is calculated relative to the total amount of the debt offering. The relative fair value of the warrants issued to the investors in the Initial Closing was determined to be $467,000, or 31.7% of the total offering. This was determined using the Black Scholes Model and the following key assumptions were used; a discount rate of 3.41%, volatility of 80.26%, 5 year expected term, and dividend yield of 0%.

The relative fair value of the warrants issued in the Initial Closing (equaling $467,000), along with the effective beneficial conversion feature of the debt in the Initial Closing of $743,000 (calculated as the difference between the conversion price specified in the Securities Purchase Agreement and the calculated intrinsic value of the conversion feature) total $1,210,000 and are not in excess of the face value of the debt. The Company is using the straight-line method to amortize the debt discount and beneficial conversion feature through the maturity dates of the convertible notes, which result does not differ materially from the effective interest rate method. For the three and nine months ended September 30, 2008, the Company has recorded additional interest expense of $619,000 and $834,000, respectively, related to the amortization of the debt discount for the Initial Closing. To the extent the debt from the Initial Closing is converted prior to maturity the amortization of the debt discount will be accelerated.

The balance of the convertible debt as of September 30, 2008 is summarized as follows:

Face amount	$ 1,475,000
Total debt discount and beneficial conversion feature	1,210,000
Amortization of debt discount and beneficial conversion feature	834,000
Net unamortized debt discount and beneficial conversion feature	376,000
Net debt recorded at September 30, 2008	$ 1,099,000

Related to the issuance of the initial offer, the Company paid debt finance costs totaling $195,000, which were capitalized as deferred financing costs. These costs will be amortized into interest expense using straight line method, which result does not differ materially from the effective interest rate method. For the three and nine months ended September 30, 2008, the Company had recorded expense of approximately $100,000 and $134,000, respectively, related to the amortization of the deferred financing costs.

The Company intends to account for the gross proceeds from the Subsequent Closing beginning in the fourth quarter 2008, in a manner comparable to that described above for the Initial Closing.

The $1,475,000 in gross proceeds from the Initial Closing, and the $2,525,000 in gross proceeds from the Subsequent Closing, were deposited into a new bank account with an account control agreement which provides that the bank will comply with the withdrawal requests originated by the Company without further consent by the Purchasers. However, if Purchasers notify the bank that the Purchasers will exercise exclusive control over the account due to an event of default on the convertible notes (a “Notice of Exclusive Control”), the bank is required to cease complying with withdrawal requests or other directions concerning the account originated by the Company. This agreement was signed by NovaDel, Purchasers and the bank. The parties entered into this agreement to perfect the Purchasers’ security interest in this account. There is no provision for the bank to monitor or restrict the use of proceeds for a particular purpose, absent a Notice of Exclusive Control as described above. Accordingly, this agreement is no different than any other collateral lien on assets. Therefore, the Company has classified these funds as part of Cash and Cash Equivalents.

NOTE 4 – CASH EQUIVALENTS

Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. At times, such investments may be in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit. Generally, these deposits may be redeemed and are maintained with high quality financial institutions, therefore reducing credit risk.

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NOTE 5 – LOSS PER SHARE

Loss per common share is computed pursuant to Statement of Financial Accounting Standards (“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 loss per common share is the same as basic loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants, and from the conversion of the convertible notes, would have an anti-dilutive effect because the Company incurred a net loss during each period presented. As of September 30, 2008 and September 30, 2007, there were 40.8 million and 37.4 million common shares, respectively, issuable upon exercise of options and warrants, the vesting of non-vested restricted common stock, and the conversion of the convertible notes, which were excluded from the diluted loss per share computation.

NOTE 6 – STOCK-BASED COMPENSATION

At September 30, 2008, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan, as amended, and the 2006 Equity Incentive Plan, as amended (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 number of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options (“ISOs”) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company’s common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant. 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 September 30, 2008, there were approximately 3.2 million shares available for issuance under the Plans.

The Company adopted the provisions of 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 costs 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 nine months ended September 30, 2008 is as follows:

Options	Shares (000)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2007	8,429	$ 1.69	5.9	
Grants	338	0.24	—	
Exercises	—	—	—	
Forfeitures	(3,253)	1.72	—	
Outstanding at September 30, 2008	5,514	$ 1.59	5.7	$ —

Vested and expected to vest at September 30, 2008	5,392	$ 1.59	5.6	$ —
Exercisable at September 30, 2008	3,071	$ 1.75	4.5	$ —

The Company recorded share-based compensation expense using the fair value method required by SFAS 123R of approximately $184,000 or $0.003 per share, and $600,000 or $0.01 per share for the three and nine months ended September 30, 2008, respectively. The Company recorded a credit of $309,000 or $0.01 per share, and expense of $622,000 or $0.01 per share, for the three and nine months ended September 30, 2007, respectively. All such amounts are included in the Company's net loss for each period.

On February 6, 2008, the Company's Board of Directors, upon the recommendation of the Compensation Committee, approved grants of 750,000 shares of restricted common stock to the executive officers of the Company and an additional 350,000 shares of restricted stock to other employees of the Company. The restricted stock was awarded from the Company's 1998 Stock Option Plan. The restrictions on the restricted stock shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a $5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional $5 million (or $10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a $20 million (or $20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse. Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of Mr. Ratoff, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a $5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional $5 million (or $10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares of restricted stock shall lapse over a three-year period.

A summary of the status of the Company's non-vested restricted common stock as of September 30, 2008 and changes during the nine months ended September 30, 2008 is presented below:

Non-Vested Restricted Common Stock	**Shares (000)**	**Weighted Average Grant-Date Fair Value**
January 1, 2008	100	$1.71
Granted	1,100	$0.47
September 30, 2008	1,200	$0.57

As of September 30, 2008, unamortized share-based compensation expense of $1.7 million remains to be recognized, which is comprised of $540,000 related to non-performance based stock options to be recognized over a weighted average period of 1.3 years, $470,000 related to restricted stock to be recognized over a weighted average period of 2.2 years, and $739,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

The Company used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants of all stock options in the respective periods:

	Three Months Ended	**Nine Months Ended**

	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Expected volatility	83%	—	83%	62%
Dividend yield	0%	—	0%	0%
Expected term (years)	3.7	—	3.7	4.9
Risk-free interest rate	2.3%	—	2.3%	4.8%

The above table represents the weighted-average assumptions for all stock options granted during the three and nine months ended September 30, 2008 and September 30, 2007. The Company granted 337,500 stock options during the three and nine months ended September 30, 2008. During the nine months ended September 30, 2007, the Company granted 3.2 million options to employees and directors, including 667,000 performance-based stock options. The Company used the following weighed average assumptions in determining the fair value for such performance-based options granted in 2007: expected volatility of 57%; dividend yield of 0%; expected term of 2.7 years; and risk-free interest rate of 4.6%. The Company granted no stock options during the three months ended September 30, 2007.

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 its current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was $0.93 during the nine months ended September 30, 2007. The total intrinsic value of options exercised was $168,000 during the nine months ended September 30, 2007. No options were exercised during the nine months ended September 30, 2008 or during the three months ended September 30, 2007.

NOTE 7 - RELATED PARTY TRANSACTIONS AND LICENSE AND DEVELOPMENT AGREEMENTS

License and Development Agreements with Unrelated Parties

BioAlliance. On May 19, 2008, the Company and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for NovaDel's Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid NovaDel a license fee of $3,000,000 upon closing. The Company is eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. BioAlliance and the Company anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. The Company will be responsible for supplying the product. The upfront payment has been included in deferred revenue and is being recognized in income over the term of the agreement (nineteen and one half-years). During the three and nine months ended September 30, 2008, the Company recognized $38,000 and $58,000 of income related to this contract, respectively.

License and Development Agreements with Related Parties

Hana Biosciences, Inc/Par Pharmaceutical, Inc. In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences, Inc. ("Hana Biosciences") an exclusive license to develop and market Zensana™, 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 fair value of the common stock received from Hana Biosciences was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, the Company, entered into a Product Development and Commercialization Sublicense Agreement (the "Sublicense Agreement") with Hana Biosciences and Par Pharmaceutical, Inc. ("Par"), pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™ (the "Amended and Restated License Agreement") to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities

of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada.

In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock, with a fair value of $140,000, that had been acquired by the Company in connection with execution of the original License Agreement (See Note 8).

During the three months ended March 31, 2007, the Company recorded a $360,000 impairment charge to the statement of operations, the only component of other loss, to establish a new cost basis of $140,000 for the investment as of March 31, 2007. The remaining investment balance was written off in the quarter ended September 30, 2007, to reflect the surrender of the Company's 73,121 shares to Hana in connection with the Amended and Restated License Agreement (See Note 8). The Company may receive additional milestone payments and royalties over the term of the agreement.

Velcera. 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 is being 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 in Velcera which did not have a material value. Such investment continues to be carried at its cost basis of $0 as of September 30, 2008. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement called for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist™ platform, which is based on its patented oral spray technology. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. In November 2007, the common stock of the merged companies began trading on the OTC bulletin board. On March 5, 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause. On October 17, 2008, Velcera announced that it had filed a Form 15 with the SEC, as a result of which Velcera's obligation to file reports with the SEC has terminated.

Manhattan Pharmaceuticals, Inc. 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. In July 2007, Manhattan Pharmaceuticals, the Company's partner for its propofol oral spray product candidate, announced that as part of its change in strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate.

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.

Other Related Party Transactions

In September 2006, the Company's Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement is on a month-to-month basis and has compensated Mr. Ratoff at a rate of between $10,000 and $17,500 per month depending upon the amount of his involvement at the Company. The rate as of September 30, 2008 is $17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff approximately $52,500 and $157,500 for the three and nine months ended September 30, 2008, respectively, and approximately $53,000 and $139,000 for the three and nine months ended September 30, 2007, respectively, for services rendered during such periods.

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In September 2007, the Company entered into a Separation, Consulting and General Release Agreement with Jan Egberts, M.D., the Company's former President, Chief Executive Officer and Director ("Dr. Egberts' Consulting Agreement"). Under the terms of Dr. Egberts' Consulting Agreement, Dr. Egberts provided the Company with certain consulting services for a period of twelve (12) months, ending July 25, 2008 (the "Term"). Dr. Egberts received fees for such services at a rate of $363,000 per annum, payable in equal biweekly installments during the Term, and was to be reimbursed for certain expenses. In addition, options previously granted to Dr. Egberts which were outstanding as of July 25, 2007 but not otherwise vested and exercisable, immediately vested and became exercisable under Dr. Egberts' Consulting Agreement and remained outstanding until the expiration of the Term (See Note 6). As Dr. Egberts did not elect to exercise such options, they expired on July 25, 2008. Pursuant to Dr. Egberts' Consulting Agreement, the Company paid Dr. Egberts $41,900 and $223,400 for the three and nine months ended September 30, 2008, respectively. The Company paid Dr. Egberts $61,000 for the three and nine months ended September 30, 2007.

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 NitroMist™, its nitroglycerin lingual spray in the U.S. and Canada. The Company has received upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment was included in deferred revenue and is being recognized in income over the 10-year term of the agreement. In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™. In the quarter ended September 30, 2007, the Company recorded $177,000 of revenue to write-off the remaining deferred revenue relating to this agreement.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies NitroMist™. For a five-year period that began November 18, 2004, INyX was to be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it would be INyX's responsibility to manufacture, package and supply NitroMist™ in such territories. Thereafter, INyX would have a non-exclusive right to manufacture such spray for an additional five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company was informed by the trustees for INyX in June 2008 that the facility in Puerto Rico where manufacturing operations for NitroMist™ were conducted would be ceasing operations as of the end of July 2008. As a result, the Company selected an alternative contract manufacturing company, DPT Laboratories Inc ("DPT"), and has transferred manufacturing operations for NitroMist™ to DPT. In connection with transferring such operations, the Company determined during the quarter ended June 30, 2008 that approximately $183,000 of the remaining equipment, and $129,000 of the inventory in Puerto Rico would no longer be of any value for continued production at the alternative manufacturing location. The total amount of the equipment and inventory disposal, inclusive of approximately $30,000 for the anticipated costs of disposal, was recognized as a loss on disposal of assets totaling $342,000 during the quarter ended June 30, 2008. The Company recognized an additional $9,000 of expense associated with the costs of disposal during the quarter ended September 30, 2008.

NOTE 8 – OTHER INCOME/(LOSS)

The following table summarizes the components of Other Income/(Loss) for the three and nine months ended September 30, 2008 and September 30, 2007, respectively:

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Other than temporary impairment of investment in marketable equity security	$ —	$ —	$ —	$ (360,000)

Loss from return of investment in marketable equity security to issuer	—	(140,000)	—	(140,000)
Write-off of deferred revenue relating to investment in marketable equity security	—	434,000	—	434,000
Total Other Income/(Loss)	$ —	$ 294,000	$ —	$ (66,000)

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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). During the three months ended March 31, 2007, the Company determined that the decline in value of this investment was other than temporary, and recorded a $360,000 impairment charge to the condensed statement of operations, establishing a new cost basis of $140,000 for the investment as of March 31, 2007. During the three months ended September 30, 2007, as a result of the Amended and Restated License Agreement with Hana Biosciences as described in Note 7, the Company recorded a $140,000 charge to expense to account for the return of Hana Biosciences' shares.

NOTE 9 – SUBSEQUENT EVENTS

On October 17, 2008, the Company closed on the remaining portion of the 2008 Financing, in the amount of $2,525,000 of convertible notes and accompanying warrants, yielding net proceeds to the Company of approximately $2.5 million, after deducting fees and estimated expenses.

In the Subsequent Closing, the Company issued the convertible notes, which convert into 10,744,681 shares of its common stock at a fixed price of $0.235 per share subject to certain adjustments, and five-year warrants to purchase 6,446,809 shares of its common stock, with an exercise price of $0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing is April 17, 2009.

The securities sold in this private placement have not been registered under the Securities Act of 1933, as amended, referred to herein as the Securities Act, and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from the registration requirements under the Securities Act. In accordance with the terms of the Securities Purchase Agreement, the Company has agreed to file a resale registration statement on Form S-3 within 30 days of the closing date to register, pursuant to the Securities Act, the shares of common stock underlying the convertible notes and warrants, acquired by the investors.

ITEM 2. MANAGEMENT'S 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 on Form 10-Q. 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 developing oral spray formulations for a broad range of marketed drugs. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have eight patents which have been issued in the U.S. and 71 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing for our product candidates.

We have had a history of recurring losses, giving rise to an accumulated deficit as of September 30, 2008 of $72,920,000, as compared to $65,243,000 as of December 31, 2007. We have had negative cash flow from operating activities of $5,126,000 and $12,051,000 for the nine months ended September 30, 2008 and September 30, 2007, respectively. As of September 30, 2008, we had working capital of $1,020,000, as compared to $3,811,000 as of December 31, 2007, representing a net decrease in working capital of approximately $2,791,000.

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During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments, and received $2,525,000 in gross proceeds on October 17, 2008, from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000.

Given the current level of spending, and assuming that ProQuest does not convert its notes into common stock, but demands payment under the notes issued in the Initial Closing and the Subsequent Closing, we estimate that we will have sufficient cash on hand to fund operations through December 2008. In the event, however, that ProQuest converts its notes into shares of common stock, then we estimate that we will have sufficient cash on hand to fund operations through the second quarter of 2009. We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations through the second quarter of 2009. We may choose to raise additional capital before December 31, 2008, or in early 2009, to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities.

Given the recent downturn in the economy, there can be no assurance that public or private 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 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 audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. We believe that the cash inflows that have been generated from the 2008 Financing, along with the $3,000,000 non-refundable license fee received from BioAlliance and any additional potential cash inflows that may be received during the remainder of 2008 and early 2009, will improve our ability to continue our operations as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty.

On May 14, 2008, we received notice from the NYSE Alternext indicating that we were not in compliance with certain of the NYSE Alternext continued listing standards. Specifically, the NYSE Alternext has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Alternext Company Guide with stockholders' equity of less than $6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years, and Section 1003(a)(iv) of the NYSE Alternext Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Alternext, as to whether we will be able to continue operations and/or meet our obligations as they mature.

In order for us to maintain our NYSE Alternext listing, we were required to submit a plan by June 13, 2008, advising the NYSE Alternext of the actions we have taken, or will take, that will bring us into compliance with Section 1003(a)(iv) by November 14, 2008, and Section 1003(a)(iii) by November 16, 2009. We informed the NYSE Alternext that we intended to submit such a plan, and did so on June 12, 2008.

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On July 30, 2008, NYSE Alternext notified us that the NYSE Alternext had completed its review of our proposed plan of compliance and supporting documentation and has determined that, although we are not in compliance with the continued listing standards of the NYSE Alternext, we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Alternext is continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of September 30, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Alternext Company Guide with stockholders' equity of less than $4,000,000 and losses from continuing operations and net losses in three of its four most recent fiscal years; and Section 1003(a)(i) of the NYSE Alternext Company Guide with stockholders' equity of less than $2,000,000 and losses from continuing operations and net losses in two of its three most recent fiscal years. However, as previously noted, the plan that we submitted to the NYSE Alternext on June 13, 2008 reasonably demonstrates our ability to attain a stockholders' equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

We will be subject to periodic review by the NYSE Alternext during the plan periods and must continue to provide the NYSE Alternext with updates in conjunction with the initiatives of the plan as appropriate or upon request, and failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in delisting from the NYSE Alternext.

There can be no assurance that we will be able to make progress consistent with our plan to regain compliance with NYSE Alternext's continued listing standards in a timely manner, or at all. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE Alternext Company Guide.

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.

Highlights for the nine months ended September 30, 2008, and additionally through the date of filing of this Quarterly Report on Form 10-Q, include the following:

Product Pipeline

- § Announced that our New Drug Application for Zolpimist™ to treat insomnia was accepted for filing by the U.S. Food and Drug Administration.

- § Announced the results of a clinical study comparing our tizanidine oral spray with tizanidine tablets, where our oral spray met primary pharmacokinetic and pharmacodynamic and safety objectives.

- § Announced the results of a pilot efficacy study comparing our NVD-201 with Imitrex® tablets, where our oral spray was safe and effective in relieving migraine headaches at a lower dosage than that for the Imitrex® tablets.

- § Announced that the U.S. Food and Drug Administration had requested an extension of up to three months on our New Drug Application for Zolpimist™ in order to complete their review.

§ Updated our website and corporate presentation for our new product pipeline, as discussed further below.

§ Announced that Par Pharmaceuticals had recently completed bioequivalence studies on Zensana™ with mixed results, and that Par would be working with us to carefully review and understand the results of the studies before determining the next steps for Zensana™.

Other

- § Announced that we had entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P. for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock.

- § Announced that we had entered into a European partnership with BioAlliance Pharma SA for the development and commercialization of our ondansetron oral spray (or OS) for Europe.

- § Announced that we had entered into amendment no. 1 to the securities purchase agreement in connection with the 2008 Financing to clarify certain terms of the securities purchase agreement.

- § Announced that we had closed the initial portion of the 2008 Financing (the Initial Closing) for an aggregate gross proceeds of $1,475,000, in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

- § Announced that we received a notification from NYSE Alternext that we were not in compliance with certain of the NYSE Alternext continued listing standards. On June 12, 2008, we submitted a plan of compliance to the NYSE Alternext for review. On July 30, 2008, NYSE Alternext notified us that it had completed its review of our proposed plan of compliance and has determined that we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods. The NYSE Alternext is continuing our listing pursuant to an extension, subject to certain conditions.

- § Announced that we had closed on the subsequent portion of the 2008 Financing (the Subsequent Closing) for aggregate gross proceeds of $2,525,000 in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or 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 a New Drug Application, or 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 submission of an NDA, will require significantly less time and 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 or changes in the regulatory approval process;
- 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. The following table summarizes our product candidates:

	Active Ingredient or Class of Molecule	**Indications**	**Stage of Development**	**Partner**
Approved Product				
NitroMist™	nitroglycerin	Angina Pectoris	FDA Approved	-
Product Candidates				
Zolpimist™	zolpidem	Insomnia Nausea/Vomiting	NDA submitted – FDA acceptance January 23, 2008 Clinical development	- Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.

Zensana™	ondansetron			
NVD-201	sumatriptan	Migraines	Pilot Efficacy study complete	-
Zolpimist™	zolpidem	Middle-of-the-Night Awakening	Clinical development	-
NVD-301	midazolam	Pre-Procedure Anxiety	Preclinical development	-
NVD-401	sildenafil	Erectile Dysfunction	Preclinical development	-
NVD-501	fentanyl	Breakthrough Pain	Preclinical development	-

NitroMist™ (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceutical, Inc., or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. We are currently investigating strategic partners for this product.

Zolpimist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hytic marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects, completed in the first half of calendar 2005, suggested that our formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. In October 2006, we announced positive results from a pilot pharmacokinetic study comparing our formulation of Zolpimist™ to Ambien® tablets. In the study, 10 healthy male volunteers received Zolpimist™ or Ambien® tablets in 5mg or 10mg doses. For fasting subjects, fifteen minutes after dosing, 80% of subjects using Zolpimist™ achieved blood concentrations of greater than 20 ng/ml, compared to 33% of subjects in the 5mg Ambien® tablet group and 40% of subjects in the 10mg Ambien® tablet group. The difference between the oral spray groups and tablet groups was statistically significant (p=0.016). Twenty ng/ml is a level generally believed to approximate the lower limit of the therapeutic range for zolpidem. Additionally, drug concentrations were measured at five and ten minutes post-dosing. At these early time points, the oral spray groups achieved drug levels five-to-thirty times greater than subjects in the corresponding tablet groups. These differences were also statistically significant. Zolpimist™ has the potential to provide patients with the meaningful benefit of faster onset of sleep as compared to existing sleep remedies should future studies validate the already completed Pilot PK study. We submitted the NDA for our zolpidem product candidate in the second half of 2007, and the FDA indicated acceptance of this NDA filing in January 2008. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA in order to complete their review. We may obtain final approval from the FDA by the fourth quarter of 2008.

Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par has previously announced that it expects to complete clinical development on the revised formulation of Zensana™ during 2008, and expects to submit a new NDA for Zensana™ by the end of 2008. However, Par recently announced that it had completed bioequivalency studies on Zensana™ with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. The Company is working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™. Scale-up and stability studies for Zensana™ to date are sufficient for NDA submission.

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 and such NDA was accepted for review by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive double-digit royalty payments based upon a percentage of net sales. We retain the rights to our ondansetron oral spray outside of the U.S. and Canada.

Sumatriptan oral spray (NVD-201). Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, or GSK. A pilot PK study of NVD-201 with 9 healthy subjects, completed in the second half of calendar 2004, suggested that the formulation achieved plasma concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from an additional pilot pharmacokinetic study, with NVD-201 which demonstrated that NVD-201 achieves a statistically significant increase in absorption rate as compared with Imitrex® tablets. The rate of drug absorption is believed to be the most important predictor of the degree and speed of migraine relief. NVD-201 was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the NVD-201 in 10 healthy male volunteers under fasting conditions. At least 90% of subjects receiving NVD-201 had detectable drug levels at three minutes post-dosing, while at the same timepoint, only 10% of subjects receiving 50mg Imitrex® tablets had detectable drug levels. These differences are statistically significant. At 3 to 6 minutes post dosing, all NVD-201 groups had statistically significantly higher mean concentration levels compared to 50mg Imitrex® tablets. Using published data for the currently marketed Imitrex® nasal spray as a proxy for therapeutic blood levels, we observed that by 6 minutes post-dosing, 100% of the 20mg NVD-201 users achieved these critical plasma concentration levels while none of the subjects from the Imitrex® tablet group did so by this timepoint. This result was also statistically significant. Furthermore, the study indicates up to a 50% increase in relative bioavailability of NVD-201 in comparison to the Imitrex® tablet. Additionally, the pharmacokinetics of 20mg NVD-201 after a meal were evaluated. NVD-201 was well tolerated.

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg NVD-201 than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the NVD-201 than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg NVD-201 appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

In September 2008 we announced the results from a pilot efficacy study for NVD-201. This was a multi-center, active control, open-label, dose-ranging, efficacy and safety study. Subjects received up to 5 treatments, comprising single doses of the following: Imigran® 50-mg tablets, Imigran® 100-mg tablets, NVD-201 20-mg, NVD-201 30-mg, and NVD-201 40-mg. Their response to Imigran® 50-mg tablets determined whether they were eligible to receive the other four treatments. Patients recorded the severity of each migraine attack on the same 4-point scale immediately before dosing and at 15, 30, 60, 90, 120, and 240 minutes, and at 24 hours post-dosing. Associated symptoms (nausea, vomiting, photophobia, and phonophobia) were also recorded immediately before dosing and at 30, 60, 90 and 120 minutes post-dosing. All dosing was done on an outpatient basis and patients returned to the clinic between migraine attacks.

In the primary analysis of efficacy, the percentage of patients responding to treatment at or before 60 minutes post-dosing, there was a statistically significant greater percentage of subjects receiving the 30- and 40-mg doses of NVD-201 with a reduction in headache pain compared to those receiving the 50-mg s Imigran® tablet (42% and 46%, respectively, vs 12%; $P \leq 0.011$), and was comparable to the percentage who responded to the higher (100 mg) dose of the tablet formulation (42%). Significantly more patients had responded to all three doses of NVD-201 than to 50-mg Imigran® tablet by 90 minutes post-dosing (57% to 70.0% vs 32%; $P \leq 0.028$) and all three oral spray doses were comparable to the 100-mg tablet. There were no treatment differences by 2 hours after dosing, when 68% to 77% of patients had responded irrespective of treatment.

Compared to 50-mg Imigran® tablet, at least one dose of NVD-201 also significantly increased percentage of patients who were pain free by 1 to 2 hours post-dosing, with the response ratio indicating significantly faster complete pain relief for the 40-mg dose, and significantly more patients had complete pain relief without use of rescue medication after receiving any dose of NVD-201. In addition, after one or more doses of NVD-201, the percentage of patients who were asymptomatic was significantly increased, and the percentages who experienced nausea, photophobia, or phonophobia were significantly decreased. NVD-201 was comparable to the 100-mg tablet on all the above measures.

We believe NVD-201 may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, we believe NVD-201 may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due primarily to funding constraints, at the present time, we are unable to make predictions for this program relative to sufficient funding, timing, future strategic partnerships, regulatory pathway or approval with the FDA. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including sumatriptan, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured sufficient additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Zolpimist™ for Middle-of-the-Night Awakenings (MOTN). Clinical studies have demonstrated that a low dose of zolpidem is effective in treating a subset of insomnia patients who wake up during the night and have difficulty falling back to sleep. We have begun development of a lower dose version of Zolpimist™ with the intent of performing clinical trials to demonstrate the benefit of an easy-to-use oral spray form of zolpidem in this important and large patient population.

Midazolam oral spray (NVD-301). NVD-301 contains midazolam which is the leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an easy-to use, rapid onset product useful to relieve the pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices.

Annually, there are approximately 40 million invasive procedures performed in the ambulatory surgical setting, > 25 million MRI/CT scans and over 90 million pediatric dental procedures performed. Pre- procedure anxiety occurs in approximately 60% of children undergoing surgery and is associated with an increase in post-surgical complications including delirium, pain and sleep disorders, as well as higher levels of use of post-surgical medications. Anxiety interferes with approximately 30% of MRI scans with 5-10% of scans not completed due to anxiety. Pre-procedure anxiety is the number one reason for the use of sedation in dental procedures.

We are completing development of a clinical formulation and expect to enter the clinic in 2009 with NVD-301, assuming that funding for clinical trials is available.

Sildenafil oral spray (NVD-401) NVD-401 contains sildenafil, the leading PDE-5 inhibitor for the treatment of erectile dysfunction marketed under the brand name Viagra®. We believe that an oral spray of sildenafil has the potential of a faster onset of action and a lower dose compared to tablets.

Erectile dysfunction occurs in approximately 18% of the male population with prevalence of over 50% in men over 65 years of age. PDE-5 inhibitors are effective in approximately 75% of the erectile dysfunction population. Sildenafil is the most popular molecule with over 50% market share in a erectile dysfunction market of over $3 billion.

Development is in progress for a formulation to be used in future clinical trials to begin in 2009, assuming that funding for such trials is available.

Fentanyl orals spray (NVD-501) NVD-501 contains fentanyl a leading opiate for the treatment of pain. We plan to develop NVD-501 as a fast acting, easy-to-use product for the treatment of break through pain in cancer patients.

Pain is a common morbidity in cancer patients occurring in approximately 30% of newly diagnosed patients and 65-85% of advanced cancer patients. Opiates are commonly used to treat cancer pain, however approximately 65% of opiate treated cancer patients have acute pain episodes, called breakthrough cancer pain, which requires the use of a short-acting drug on top of the patients' basic pain therapy regimen. There are two products approved in the United States for the treatment of breakthrough cancer pain with combined sales of approximately $500 million. The global market for breakthrough cancer products is predicted to grow to over $2 billion by 2016.

Formulation development is ongoing with the objective of entering clinical trials in 2009, assuming that funding for such trials is available.

Ondansetron oral spray (Europe) - On May 19, 2008, we entered into a European partnership for our ondansetron oral spray for the treatment of nausea with BioAlliance Pharma SA. The agreement with BioAlliance resulted in an immediate non-refundable license fee to us of $3 million, with up to an aggregate of $24 million in additional milestones in addition to royalties expected upon the approval and commercialization of the product by BioAlliance.

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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, which 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 were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in view of the higher priority associated with our current product pipeline as described above, we do not anticipate further development of tizanidine oral spray due to commercial and operational priorities.

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 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 were previously targeting an NDA submission for our ropinirole product candidate in calendar 2008. However, in view of the higher priority associated with our current product pipeline as described above, we do not anticipate further development of ropinirole oral spray due to commercial and operational priorities.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous 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 candidate. On July 10, 2007, Manhattan Pharmaceuticals announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Veterinary. Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera’s Promist™ platform, which is based on our patented oral spray technology. On March 5, 2008, Velcera announced that it had received notice from Novartis that it was terminating the agreement without cause.

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.

CRITICAL ACCOUNTING POLICIES

USE OF ESTIMATES - The accompanying condensed 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 condensed financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the condensed financial statements giving due regard to materiality.

CASH AND CASH EQUIVALENTS – Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. We maintain our cash and cash equivalents with several financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed on demand and are maintained with high quality financial institutions, therefore reducing credit risk.

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.

DEFERRED FINANCING COSTS – We capitalize the costs related to the issuance of our convertible notes, and amortize such deferred costs to interest expense on a straight-line basis over the life of the related notes. We capitalized approximately $195,000 of deferred financing costs associated with the issuance of our convertible notes during the quarter ended June 30, 2008, and amortized approximately $100,000 and $134,000 to expense during the three and nine months ended September 30, 2008, respectively.

WARRANTS ISSUED WITH CONVERTIBLE NOTES – We account for the value of warrants and the intrinsic value of beneficial conversion rights arising from the issuance of convertible notes pursuant to the consensuses for EITF Issue No. 98-5, EITF Issue No. 00-19 and EITF Issue No. 00-27. Such values are determined by allocating an appropriate portion of the proceeds received from the debt instruments to the debt and warrants based on their relative fair value, which was determined using the Black-Scholes model.

VALUATION OF LONG-LIVED ASSETS – We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Our long-lived assets as of September 30, 2008 were represented by property and equipment, as we have no intangible assets on our balance sheet. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management's best estimate using appropriate assumptions and projections at that time. Net long-lived property and equipment as of September 30, 2008 was $1.6 million. We reviewed our long-lived property and equipment as of September 30, 2008, and have determined that their estimated fair value exceeds the carrying amount of such assets; therefore, we have not recognized an impairment loss for our long-lived property and equipment.

STOCK-BASED COMPENSATION – We have adopted the provisions of SFAS, No. 123, 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. Using the fair value method required by SFAS 123R, we recorded share-based compensation expense of $184,000, or $0.003 per share, and $600,000, or $0.01 per share, for the three and nine months ended September 30, 2008. We recorded a credit of $309,000 or $0.01 per share, and expense of $622,000, or $0.01 per share, for the three and nine months ended September 30, 2007, respectively. We will continue to incur share-based compensation charges in future periods. As of September 30, 2008, unamortized stock-based compensation expense of $1.7 million remains to be recognized, which is comprised of $540,000 related to non-performance based stock options to be recognized over a weighted average period of 1.3 years, $470,000 related to restricted stock to be recognized over a weighted average period of 2.2 years, and $739,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when we

determine that it is probable that the milestone will be reached.

We used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants of all stock options in the respective periods:

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Expected volatility	83%	__	83%	62%
Dividend yield	0%	__	0%	0%
Expected term (years)	3.7	__	3.7	4.9
Risk-free interest rate	2.3%	__	2.3%	4.8%

The above table represents the weighted-average assumptions for all stock options granted during the three and nine months ended September 30, 2008 and September 30, 2007. We granted 337,500 stock options during the three and nine months ended September 30, 2008. During the nine months ended September 30, 2007, we granted 3.2 million options to employees and directors, including 667,000 performance-based stock options. We used the following weighted average assumptions in determining the fair value for such performance-based options granted in 2007: expected volatility of 57%; dividend yield of 0%; expected term of 2.7 years; and risk-free interest rate of 4.6%. We granted no stock options during the three months ended September 30, 2007.

Expected volatility is based on historical volatility of our 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. We are utilizing a 5% forfeiture rate, which we believe 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, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was $0.93 during the nine months ended September 30, 2007. The total intrinsic value of options exercised was $168,000 during the nine months ended September 30, 2007. No options were exercised during the nine months ended September 30, 2008 or during the three months ended September 30, 2007.

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

RESULTS OF OPERATIONS

NINE MONTHS ENDED SEPTEMBER 30, 2008 AND SEPTEMBER 30, 2007

License fees and milestone fees earned for the nine months ended September 30, 2008 were $258,000, as compared to $411,000 for the nine months ended September 30, 2007. The decrease is due to a non-recurring milestone payment received in the nine months ended September 30, 2007 from our license agreement with Velcera for veterinary products, which more than offset a one-time payment received during the first nine months of 2008 in connection with a product candidate that had been in development several years ago, and was no longer in our active product candidate pipeline.

Research and development expenses for the nine months ended September 30, 2008 were $3,151,000 as compared to $8,508,000 for the nine months ended September 30, 2007. Research and development costs consist primarily of 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 for the nine months ended September 30, 2008 and September 30, 2007.

	Nine Months Ended	
	September 30, 2008	**September 30, 2007**
NitroMist™	$96,000	$250,000
Zolpimist™	775,000	4,068,000
Sumatriptan	294,000	747,000
Zensana™	—	212,000
Tizanidine	37,000	105,000
Ropinirole	—	3,000
Other research and development costs	203,000	977,000
Internal costs	1,746,000	2,146,000
Total research and development expenses	$3,151,000	$8,508,000

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

- NitroMist™, Zolpimist™, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured sufficient additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

- Zensana™ - third-party direct project expenses relating to the development of Zensana™. As our partner for the Zensana™, Par, is overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to this product candidate. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana™, as described above, we devoted resources to this project during the nine months ended September 30, 2007, including approximately $204,000 in third-party costs;

- 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 nine months ended September 30, 2008 decreased primarily as a result of the following items:

- $3,293,000 decrease in product development costs for our Zolpimist™ product candidate, as development efforts were substantially completed during the fourth quarter 2007, including filing of an NDA. Development costs for zolpidem in the first quarter 2007 included costs for clinical trials, manufacturing preparedness and other NDA preparatory costs;

- $212,000 decrease in product development costs related to Zensana™, as noted above;

- $154,000 decrease in costs associated with our NitroMist™ product candidate primarily due to process validation and method transfer activities in the nine months ended September 30, 2007, which did not recur in the nine months ended September 30, 2008;

- $453,000 decrease in product development costs for our Sumatriptan product candidate, as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007; and

- $774,000 decrease in other research and development costs as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007.

Consulting, selling, general and administrative expenses for the nine months ended September 30, 2008 were $3,473,000 as compared to $5,539,000 for the nine months ended September 30, 2007. 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 general and administrative expenses is primarily attributable to reduced salaries, benefits and other employee-related expenses, and to lower stock compensation charges.

The loss on disposal of assets-held-for-sale was $351,000 for the nine months ended September 30, 2008, as described in Note 7.

Primarily as a result of the factors described above, total expenses for the nine months ended September 30, 2008 were $6,975,000, as compared to $14,047,000 for the nine months ended September 30, 2007.

Other Loss, net for the nine months ended September 30, 2007 was $66,000, as described in Note 8.

Interest expense for the nine months ended September 30, 2008 was $1,044,000, of which $1,019,000 related to the convertible notes that were issued during the quarter ended June 30, 2008. This included $834,000 related to the amortization of the debt discount related to the beneficial conversion feature and fair value of the warrants, as well as $134,000 related to the amortization of the deferred financing costs.

Interest income for the nine months ended September 30, 2008 was $84,000 as compared to $544,000 for the nine months ended September 30, 2007 due to lower average cash and short-term investment balances.

The resulting net loss for the nine months ended September 30, 2008 was $7,677,000, as compared to $13,158,000 for the nine months ended September 30, 2007.

THREE MONTHS ENDED SEPTEMBER 30, 2008 AND SEPTEMBER 30, 2007

License fees and milestone fees earned for the three months ended September 30, 2008 were $104,000, as compared to $206,000 for the three months ended September 30, 2007. License and milestone fees in 2007 included $177,000 associated with recognizing all remaining deferred revenue from our agreement with Par Pharmaceuticals on our NitroMist™ product, as Par returned the rights to that product line to us on August 1, 2007.

Research and development expenses for the three months ended September 30, 2008 were $705,000 as compared to $2,086,000 for the three months ended September 30, 2007. Research and development costs consist primarily of 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 for the three months ended September 30, 2008 and September 30, 2007.

	Three Months Ended	
	September 30, 2008	**September 30, 2007**
NitroMist™	$84,000	$60,000
Zolpimist™	125,000	771,000
Sumatriptan	16,000	187,000
Zensana™	—	8,000
Other research and development costs	41,000	439,000
Internal costs	439,000	621,000
Total research and development expenses	$705,000	$2,086,000

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

- NitroMist™, Zolpimist™ and Sumatriptan - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured sufficient additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

- 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 September 30, 2008 decreased primarily as a result of the following items:

- $646,000 decrease in product development costs for our Zolpimist™ product candidate, as development efforts were substantially completed during the fourth quarter 2007, including filing of an NDA. Development costs for zolpidem in the third quarter 2007 were primarily NDA preparatory costs;

- $24,000 increase in costs associated with our NitroMist™ product candidate primarily due to expenses associated with transferring production from our previous contract manufacturer, Inyx Pharma, to our new contract manufacturer, DPT Laboratories;

- $171,000 decrease in product development costs for our Sumatriptan product candidate, as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007; and

- $398,000 decrease in other research and development costs as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007.

Consulting, selling, general and administrative expenses for the three months ended September 30, 2008 were $1,164,000 as compared to $951,000 for the three months ended September 30, 2007. The expenses for the three months ended September 30, 2007 included a $542,000 credit associated with the modification and accelerated vesting of options for Dr. Jan Egberts, our former President and CEO. Exclusive of this credit, total consulting, selling, general and administrative expenses for the three months ended September 30, 2008 were $329,000 lower as compared to expenses during the three months ended September 30, 2007. 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 general and administrative expenses is primarily attributable to reduced salaries, benefits and other employee-related expenses, and to lower stock compensation charges.

The loss on disposal of assets-held-for-sale was $9,000 for the three months ended September 30, 2008, as described in Note 7.

Primarily as a result of the factors described above, total expenses for the three months ended September 30, 2008 were $1,878,000, as compared to $3,037,000 for the three months ended September 30, 2007.

Other Income, net for the three months ended September 30, 2007 is comprised of the following items:

	September 30, 2007
Loss from return of investment in marketable equity security to issuer	$ (140,000)
Write-off of deferred revenue relating to investment in marketable equity security	434,000
Total Other Income, net	$ 294,000

- $140,000 non-cash charge to account for the return of Hana Biosciences' shares, as a result of the Amended and Restated License Agreement with Hana Biosciences; and
- $434,000 benefit to write-off the remaining deferred revenue related to the shares received Hana Biosciences.

Interest expense for the three months ended September 30, 2008 was $750,000, of which $744,000 related to the convertible notes that were issued during the quarter ended June 30, 2008. This included $619,000 related to the amortization of the debt discount related to the beneficial conversion feature and fair value of the warrants, as well as $100,000 related to the amortization of the deferred financing costs.

Interest income for the three months ended September 30, 2008 was $21,000 as compared to $127,000 for the three months ended September 30, 2007 due to lower average cash and short-term investment balances.

The resulting net loss for the three months ended September 30, 2008 was $2,503,000, as compared to $2,410,000 for the three months ended September 30, 2007.

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 as of September 30, 2008 of $72,920,000, as compared to $65,243,000 as of December 31, 2007. We have had negative cash flow from operating activities of $5,126,000 and $12,051,000 for the nine months ended September 30, 2008 and September 30, 2007, respectively. As of September 30, 2008, we had working capital of $1,020,000 as compared to $3,811,000 as of September 30, 2007, representing a net decrease in working capital of approximately $2,791,000. As explained further below, such decrease is primarily due to the loss for the nine months ended September 30, 2008 of $7,677,000.

Net cash used in operating activities was $5,126,000 for the nine months ended September 30, 2008, as compared to $12,051,000 for the nine months ended September 30, 2007. The $6,925,000 decrease in cash used is primarily due to the following:

- A reduction in net loss from $13,158,000 for the nine months ended September 30, 2007 to $7,677,000 for the nine months ended September 30, 2008, representing an improvement of $5,481,000.

- $2,822,000 increase in deferred revenue for the nine months ended September 30, 2008, as compared with a decrease of $636,000 for the nine months ended September 30, 2007. The significant increase in 2008 is due to the non-refundable license fee of $3,000,000 received from BioAlliance in May 2008.

- $127,000 decrease in prepaid expenses and other current assets for the nine months ended September 30, 2008, as compared with a $378,000 increase for the nine months ended September 30, 2007. The decrease in 2008 is due to the expiration of useful life on certain prepaid operating supplies at our contract manufacturer in Sweden, primarily due to the fact that we have significantly reduced our development activities since December 2007. The increase in 2007 was associated with our increasing investments during that year in our operating supplies at the same contract manufacturer in Sweden.

- These amounts were partially offset by $2,750,000 decrease in accounts payable and accrued liabilities for the nine months ended September 30, 2008, as compared with an increase of $665,000 in the nine months ended September 30, 2007. The significant decrease in accounts payable and accrued liabilities in 2008 is due to the payment of expenses generated during the last half of 2007 for development activities. We have significantly decreased our development activities since the fourth quarter 2007.

Net cash provided by investing activities was $0 for the nine months ended September 30, 2008, as compared to $239,000 provided by investing activities for the nine months ended September 30, 2007. The difference is primarily a result of net maturities of short-term investments in the nine months ended September 30, 2007.

Cash provided by financing activities was approximately $1,151,000 for the nine months ended September 30, 2008, as compared to $1,478,000 for the nine months ended September 30, 2007. On May 6, 2008, we entered into a binding securities purchase agreement with funds affiliated with ProQuest Investments LLC to sell up to $4,000,000 of secured convertible promissory notes, of which approximately $1,475,000 was funded on May 30, 2008. This was partially offset by financing costs of $195,000 related to the secured convertible notes. During the quarter ended June 30, 2007, we received net proceeds from private placements of $1,395,000.

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 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.

During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments, and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate

non-refundable license fee of $3,000,000.

Given the current level of spending, and assuming that ProQuest does not convert its notes into common stock, but demands payment under the notes issued in the Initial Closing and the Subsequent Closing, we estimate that we will have sufficient cash on hand to fund operations through December 2008. In the event, however, that ProQuest converts its notes into shares of common stock, then the Company estimates that it will have sufficient cash to fund operations through the second quarter of 2009. We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations through the second quarter of 2009. We may choose to raise additional capital before December 31, 2008, or in early 2009, to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities.

Given the current downturn in the economy, there can be no assurance that private or public 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 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 audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. We believe that the cash inflows that have been generated from the 2008 Financing, along with the $3,000,000 non-refundable license fee paid to us by BioAlliance and any additional potential cash inflows that may be received during the remainder of 2008 and early 2009, will improve our ability to continue our operations as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty.

On May 14, 2008, we received notice from the NYSE Alternext indicating that we are not in compliance with certain of the NYSE Alternext continued listing standards. Specifically, the NYSE Alternext has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Alternext Company Guide with stockholders' equity of less than $6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years, and Section 1003(a)(iv) of the NYSE Alternext Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Alternext, as to whether we will be able to continue operations and/or meet our obligations as they mature.

In order for us to maintain our NYSE Alternext listing, we were required to submit a plan by June 13, 2008, advising the NYSE Alternext of the actions we have taken, or will take, that will bring us into compliance with Section 1003(a)(iv) by November 14, 2008, and Section 1003(a)(iii) by November 16, 2009. We informed the NYSE Alternext that we intended to submit such a plan, and did so on June 12, 2008.

On July 30, 2008, NYSE Alternext notified us that the NYSE Alternext had completed its review of our proposed plan of compliance and supporting documentation and has determined that, although we are not in compliance with the continued listing standards of the NYSE Alternext, we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Alternext is continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of September 30, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Alternext Company Guide with stockholders' equity of less than $4,000,000 and losses from continuing operations and net losses in three of its four most recent fiscal years; and Section 1003(a)(i) of the NYSE Alternext Company Guide with stockholders' equity of less than $2,000,000 and losses from continuing

operations and net losses in two of its three most recent fiscal years. However, as previously noted, the Plan that we submitted to the NYSE Alternext on June 13, 2008 reasonably demonstrates our ability to attain a stockholders' equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

We will be subject to periodic review by the NYSE Alternext during the plan periods and must continue to provide the NYSE Alternext with updates in conjunction with the initiatives of the plan as appropriate or upon request, and failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in delisting from the NYSE Alternext.

There can be no assurance that we will be able to make progress consistent with our plan to regain compliance with NYSE Alternext's continued listing standards in a timely manner, or at all. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE Alternext Company Guide.

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 December 31, 2007, there have been no material changes with respect to our contractual obligations as disclosed in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2007 and as supplemented by our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2008, June 30, 2008 and September 30, 2008.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest primarily in short-term, highly-rated investments, including U.S. government securities and certificates of deposit guaranteed by banks. Our market risk exposure consists principally of exposure to changes in interest rates. Because of the short-term maturities of our investments, however, we do not believe that a decrease in interest rates would have a significant negative impact on the value of our investment portfolio.

ITEM 4T. 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 September 30, 2008. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of September 30, 2008, our disclosure controls and procedures wereeffective in that they were designed to ensure that material information relating to us is made known to our Chief Executive Officer and Chief Financial Officer by others within the Company, as appropriate to allow timely decisions regarding required disclosures, and 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 September 30, 2008, 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 report, and in any documents incorporated in this report by reference.

RISKS RELATED TO OUR BUSINESS

OUR AUDITORS HAVE EXPRESSED SUBSTANTIAL DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our unaudited condensed financial statements for the nine months ended September 30, 2008, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, and preclinical studies.

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007, we believe that we will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000.

Given the recent downturn in the economy, 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 obtain additional financing on terms acceptable to us, or at all. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

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If we are unable to raise additional funds, we will need to do one or more of the following:

- further delay, scale-back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We may continue to maintain current levels of spending during the fiscal year 2008, given the uncertainties inherent in our business and our current liquidity position. We believe that at the current level of spending, and assuming that ProQuest does not convert its notes into common stock, but demands payment under the notes issued in the Initial Closing and the Subsequent Closing, we estimate that we will have sufficient cash on hand to fund operations through December 2008. In the event, however, that ProQuest converts its notes into shares of common stock, we estimate that we will have sufficient cash on hand to fund operations through the second quarter of 2009. We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations through the second quarter of 2009. We may choose to raise additional capital before December 31, 2008, or in early 2009, to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. There can be no assurance that such capital will be available to us on favorable terms, or at all.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION IN THE NEAR TERM.

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 current and future partners, and royalty payments from sales of approved product candidates by partners. Given the recent downturn in the economy, we can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no

assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000.

Given the current level of spending, and assuming that ProQuest does not convert its notes into common stock, but demands payment under the notes issued in the Initial Closing and the Subsequent Closing, we estimate that we will have sufficient cash on hand to fund operations through December 2008. In the event, however, that ProQuest converts its notes into shares of common stock, we estimate that we will have sufficient cash on hand to fund operations through the second quarter of 2009. We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations through the second quarter of 2009. We may choose to raise additional capital before December 31, 2008, or in early 2009, to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. Given the recent downturn in the economy, 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 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.

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 developing oral spray formulations of a broad range of marketed treatments. 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 U.S. Food and 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™. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist™, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist™ in order to complete their review. Based on the FDA acceptance, and the subsequent extension, we would anticipate a final response from the FDA in December, 2008. We are currently investigating strategic partners for both NitroMist™ and Zolpimist™. 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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. Given the recent downturn in the economy, there can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

We had an accumulated deficit as of September 30, 2008 of approximately $72,920,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $7,677,000 for the nine months ended September 30, 2008, $16,963,000 for the year ended December 31, 2007, $3,805,000 for the five months ended December 31, 2006, $10,084,000 for the fiscal year ended July 31, 2006 and $9,450,000 for the fiscal year ended July 31, 2005. Additionally, we have reported negative cash flows from operations of approximately $5,126,000 for the nine months ended September 30, 2008, $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five months ended December 31, 2006, $8,855,000 for the fiscal year ended July 31, 2006 and $6,258,000 for the fiscal year ended July 31, 2005. 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.

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. Given the recent downturn in the economy, 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 200,000,000 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.

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.

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.

As of September 30, 2008, ProQuest Investments, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 23.2% of our outstanding common stock (assuming exercise of certain warrants held by ProQuest Investments). In addition, 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 September 30, 2008, Dr. Rosenwald beneficially owns approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald).

As such, ProQuest Investments, 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 NYSE Alternext, 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 various private placements. 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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. Given the recent downturn in the economy, there can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities. 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 the calendar year 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist™, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist™ in order to complete their review. Based on the FDA acceptance, and the subsequent extension, we would anticipate a final response from the FDA in December, 2008. We are currently investigating strategic partners for both NitroMist™ and Zolpimist™. Our partner for Zensana™, Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™. 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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

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. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist™, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist™ in order to complete their review. Based on the FDA acceptance, and the subsequent extension, we would anticipate a final response from the FDA in December, 2008. We are currently investigating strategic partners for both NitroMist™ and Zolpimist™. Our partner for Zensana™, Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™. 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. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

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., whereby Inyx shall manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. On July 3, 2007, INyX, our manufacturer for our NitroMist™ product candidate, announced it filed for protection under the Chapter 11 bankruptcy laws. In June 2008, the trustees for INyX informed us that the facility in Manati, Puerto Rico would cease operations at the end of July 2008. As a result, we selected an alternative manufacturer for NitroMist™, DPT Laboratories Inc, and have transferred manufacturing operations to DPT.

In February 2008, we entered into a Master Services Agreement with Rechon Life Sciences (Malmo, Sweden), whereby Rechon will provide services related to the manufacturing development and the manufacture of clinical supplies for our products. Rechon provides these services on a fee-for-service basis.

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, DPT Laboratories, or Rechon Life Sciences 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 and financial condition could be harmed.

We are 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 reports by our independent registered public accounting firm addressing these assessments and our internal controls. 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.

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 NYSE Alternext 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 recent 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 requires 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 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.

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.

Through June 30, 2007, we entered into strategic license agreements with: (i) Hana Biosciences, for the marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par for the marketing rights in the U.S. and Canada for our nitroglycerin oral spray, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. Subsequent to June 30, 2007, the following events occurred with respect our strategic license agreements:

On July 10, 2007, Manhattan Pharmaceuticals announced that as part of its change in strategic focus it intends to pursue appropriate out-licensing opportunities for this product candidate.

On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, or the Sublicense Agreement, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™, our oral spray version of ondansetron. In connection therewith, we and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™, or the Amended and Restated License Agreement, to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, with us able to collaborate on development in certain instances. We retain our rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ or payments or other fees from a sublicense and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by us in connection with execution of the original License Agreement.

On July 31, 2007, we and Par agreed to terminate the Development, Manufacturing and Supply Agreement, dated July 28, 2004, or the DMS Agreement, relating to NitroMist™. Under the DMS Agreement, Par had exclusive rights to market, sell and distribute NitroMist™ in the U.S. and Canada, with us entitled to royalty payments based upon a percentage of net sales. We are currently investigating strategic partners for the commercialization of NitroMist™.

On May 19, 2008, we entered into a European partnership for our ondansetron oral spray for the treatment of nausea with BioAlliance. This product is currently in clinical development in North America under sub-license to Par, who have announced their intent to file a new drug application before the end of 2008. The agreement with BioAlliance resulted in an immediate non-refundable license fee to us of $3,000,000, with up to an aggregate of approximately $24 million in additional milestones in addition to royalties expected upon the approval and commercialization of the product by BioAlliance.

On November 7, 2008, our partner for Zensana™, Par Pharmaceuticals, announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™. Scale-up and stability results for Zensana™ to date are sufficient for NDA submission.

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, or USPTO, has not adopted a consistent policy regarding the breadth of claims that the USPTO 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 an NDA under Section 505(b)(2) for Zensana™ in June 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 trade name Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. 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. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

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 USPTO 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 71 patents which have been issued outside of the U.S. Additionally, we have over 90 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 USPTO 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 USPTO 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 USPTO 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 AND BOARD MEMBERS.

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 January 4, 2007, Mr. Barry Cohen ceased to serve as Vice President, Business and New Product Development.

On February 2, 2007, we announced the election of Mr. Mark J. Baric as a member of our Board, effective February 1, 2007.

On February 22, 2007, our Board appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.

On July 23, 2007, our Board accepted the resignation of Jan H. Egberts, M.D., President, Chief Executive Officer and Director, effective July 25, 2007.

On July 23, 2007, our Board appointed Steven B. Ratoff, our current Chairman, as Interim President and Chief Executive Officer, effective July 25, 2007.

On December 14, 2007, our Board renewed the employment agreement of Michael E. Spicer, as Chief Financial Officer and Corporate Secretary, effective December 20, 2007.

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.

RISKS RELATED TO OUR COMMON STOCK

WE RECEIVED NOTICE FROM THE AMERICAN STOCK EXCHANGE THAT WE FAILED TO COMPLY WITH CERTAIN OF ITS CONTINUED LISTING STANDARDS, WHICH MAY RESULT IN A DELISTING OF OUR COMMON STOCK FROM THE EXCHANGE.

Our common stock is currently listed for trading on the American Stock Exchange, or NYSE Alternext, and the continued listing of our common stock on the NYSE Alternext is subject to our compliance with a number of listing standards. These listing standards include the requirement for maintaining stockholders' equity of at least $6,000,000. As of September 30, 2008, our net worth position was a deficit of $1,693,000 and as of December 31, 2007, our net worth position was $4,174,000, which are each below the minimum net worth continued listing requirement. On May 14, 2008, we received a notice from NYSE Alternext providing notification that we are not in compliance with Section 1003(a)(iii) of the NYSE Alternext Company Guide with stockholder's equity of less than $6,000,000 and losses from continuing operations and net losses in the five most recent fiscal years and Section 1003(a)(iv) of the NYSE Alternext Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Alternext, as to whether we will be able to continue operations and/or meet our obligations as they mature. We submitted a plan to the NYSE Alternext on June 12, 2008 advising of the actions we have taken, and will take, that would bring us into compliance with Section 1003(a)(iii) by November 16, 2009 and Section 1003(a)(iv) by November 14, 2008. On July 30, 2008, NYSE Alternext notified us that the NYSE Alternext had completed its review of our proposed plan of compliance and supporting documentation and has determined that, although we are not in compliance with the continued listing standards of the NYSE Alternext, we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Alternext is continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of September 30, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Alternext Company Guide with stockholders' equity of less than $4,000,000 and losses from continuing operations and net losses in three of its four most recent fiscal years; and Section 1003(a)(i) of the NYSE Alternext Company Guide with stockholders' equity of less than $2,000,000 and losses from continuing operations and net losses in two of its three most recent fiscal years. However, as previously noted, the plan we submitted to the NYSE Alternext on June 13, 2008 reasonably demonstrates our ability to attain a stockholders' equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

There can be no assurance that we will be able to make progress consistent with our plan to regain compliance with NYSE Alternext's continued listing standards in a timely manner, or at all. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE Alternext Company Guide.

On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. We may also enter into additional agreements during the remainder of 2008. The combined amounts of such agreements could be sufficient to cure the deficiency in net worth position as of December 31, 2007 and September 30, 2008. We are currently reviewing several alternative sources of capital, which if successfully implemented may allow us to satisfy the NYSE Alternext listing standards. There can be no assurances that we will be able to obtain any additional capital, or on terms favorable to us, or that we will be able to maintain our continued listing on the NYSE Alternext.

If our common stock were no longer listed on the NYSE Alternext, 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.

WE ARE INFLUENCED 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. As of September 30, 2008, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 20% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, Dr. Rosenwald and ProQuest Investments have the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald also 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 NYSE Alternext, Mr. Lobell has been deemed to be an independent director by our Board 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 prospectus and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the NYSE Alternext 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 twelve-month period ended September 30, 2008, the closing price of our common stock has ranged from $0.17 to $0.54. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve-month period ended September 30, 2008, the average daily trading volume in our common stock was approximately 130,000 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 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 NYSE Alternext 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 200,000,000 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. As of September 30, 2008, there were 60,692,260 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, or the conversion of our convertible notes. As of September 30, 2008, we had outstanding stock options and warrants to purchase approximately 34.6 million shares of common stock, the exercise prices of which range between $0.21 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended , to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 34.6 million shares of common stock noted above.

On October 17, 2008, an additional $2,525,000 of secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock. We issued 6,446,809 warrants, which have an exercise price of $0.294 per share, and are not included in the total outstanding stock options and warrants to purchase approximately 34.6 million shares of common stock as of September 30, 2008 noted above.

The following table provides an overview of our stock options and corresponding plans, as of September 30, 2008:

Plan	Shares Authorized	Options Outstanding at September 30, 2008	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000	—	Plan Closed
1997 Stock Option Plan	500,000	50,000	—	Plan Closed
1998 Stock Option Plan	3,400,000	1,831,800	1,273,200	—
2006 Equity Incentive Plan	6,000,000	2,861,800	1,938,200	—
Non-Plan	n/a	730,500	n/a	—
Total		**5,514,100**	**3,211,400**	

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 six-month 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 one-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

As permitted by Delaware law, our certificate of incorporation limits the liability of our directors for monetary damages for breach of a director's fiduciary duty except for liability in certain instances. As a result of our charter provision and Delaware law, stockholders may have limited rights to recover against directors for breach of fiduciary duty. In addition, our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by law.

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

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

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

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

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

In October 2008, we sold securities in the subsequent closing of the 2008 Financing, resulting in the issuance of notes convertible into 10,744,681 shares of our common stock, and warrants to purchase 6,446,809 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $2,525,000, before deducting certain fees and expenses.

In May 2008, we sold securities in the initial closing of the 2008 Financing, resulting in the issuance of notes convertible into 5,000,000 shares of our common stock, and warrants to purchase 3,000,000 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $1,475,000, before deducting certain fees and expenses.

In December 2006, we sold securities in a private placement transaction resulting in the issuance of 9,823,983 shares of our common stock, and warrants to purchase 4,383,952 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $14.2 million, prior to offering expenses.

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 prospectus, such shelf 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 approximately $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 September 30, 2008, we have 60,692,260 shares of common stock issued and outstanding and approximately 34.6 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 34.6 million shares of common stock noted above. On October 17, 2008, $2,525,000 of additional secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock, and an additional 6,446,809 warrants were issued with an exercise price of $0.294 per share, which are not included in the 34.6 million shares of common stock for options and warrants noted above. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 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.

THE SECURITIES ISSUED IN OUR DECEMBER 2006 PRIVATE PLACEMENT AND OUR 2008 PRIVATE PLACEMENT ARE RESTRICTED SECURITIES.

At the time of the offer and sale of the common stock and the shares of common stock underlying the convertible notes and the warrants, as applicable, in our December 2006 private placement and 2008 private placement, the common stock was not registered under the Securities Act or the securities laws of any state. Accordingly, these securities may not be sold or otherwise transferred unless such sale or transfer is subsequently registered under the Securities Act and applicable state securities laws or unless exemptions from such registration are available. The registration statements covering the December 2006 private placement and the initial closing of the 2008 private placement were declared effective by the SEC on January 26, 2007 and July 16, 2008, respectively. Notwithstanding our registration obligations regarding these securities, investors may be required to hold these securities for an indefinite period of time. All investors who purchase these securities are required to make representations that it will not sell, transfer, pledge or otherwise dispose of any of the securities in the absence of an effective registration statement covering such transaction under the Securities Act and applicable state securities laws, or the receipt by us of an opinion of counsel to the effect that registration is not required.

WE HAVE BROAD DISCRETION AS TO THE USE OF THE PROCEEDS FROM THE 2008 PRIVATE PLACEMENT AND MAY USE THE PROCEEDS IN A MANNER WITH WHICH YOU DISAGREE.

Our Board and management will have broad discretion over the use of the net proceeds of the 2008 private placement (including the initial closing in May 2008 and the subsequent closing in October 2008). Stockholders may disagree with the judgment of the Board and management regarding the application of the proceeds of the May 2008 private placement. We cannot predict that investments of the proceeds will yield a favorable, or any, return.

WE MAY INCUR SIGNIFICANT COSTS FROM CLASS ACTION LITIGATION DUE TO OUR EXPECTED STOCK VOLATILITY.

In the past, following periods of large price declines in the public market price of a company’s stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

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. In addition, 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 16, 2008, January 26, 2007, May 30, 2006 and July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

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

Our annual meeting of stockholders was held on September 8, 2008. There were present at the annual meeting of stockholders in person or by proxy stockholders holding an aggregate of 54,178,781 shares of our common stock out of a total number of 60,692,260 shares of common stock issued and outstanding and entitled to vote at the meeting. Our stockholders voted on four matters, as follows:

1. The stockholders elected six directors to each serve until our 2009 annual meeting of stockholders and until their successors have been duly elected and qualified by the following votes (there were no abstentions or broker non-votes in connection with the election of the directors):

	Number of Shares of Common Stock	
	For:	**Withheld:**
Mark J. Baric	52,969,741	1,209,040
Thomas E. Bonney	53,113,237	1,065,544
William F. Hamilton, Ph.D.	52,973,515	1,205,266
J. Jay Lobell	53,119,741	1,059,040
Charles Nemeroff, M.D., Ph.D.	52,970,515	1,208,266
Steven B. Ratoff	53,125,328	1,053,453

2. The stockholders approved the issuance and sale of up to $2.525 million in secured convertible notes and warrants of the Company to funds affiliated with ProQuest Investments:

Number of Shares of Common Stock			
For:	**Against:**	**Abstain:**	**Broker Non-Votes**
33,297,863	1,565,604	157,942	19,157,372

3. The stockholders approved the potential issuance of 3,250,000 shares of the Company's common stock resulting from: (i) the removal of the cap of 19.99% on the 3,000,000 warrants issued in the Initial Closing of the ProQuest transaction; and (ii) the interest shares provision of the secured convertible notes in the Initial Closing of the ProQuest transaction:

Number of Shares of Common Stock			
For:	**Against:**	**Abstain:**	**Broker Non-Votes**
33,080,123	1,705,643	235,642	19,157,373

4. The stockholders ratified the appointment of J.H. Cohn LLP as our independent auditors for the fiscal year ending December 31, 2008 by the following votes (there were no broker non-votes in connection with the ratification of our independent auditor):

Number of Shares of Common Stock		
For:	**Against:**	**Abstain:**
53,496,129	477,902	204,750

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

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

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
31.1	Certification 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

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: November 12, 2008	By:	/s/ STEVEN B. RATOFF Steven B. Ratoff Interim President and Chief Executive Officer (principal executive officer)
Date: November 12, 2008	By:	/s/ MICHAEL E. SPICER Michael E. Spicer Chief Financial Officer (principal financial and accounting officer)