NOVADEL PHARMA INC
Form 10-Q
August 12, 2009
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 June 30, 2009

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	**22-2407152**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o 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 o (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 3, 2009, the issuer had 61,706,374 shares of common stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009

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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; inadequate supplies of drug substance and drug product; 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 JUNE 30, 2009 (UNAUDITED) AND DECEMBER 31, 2008

ASSETS	**June 30, 2009**	**December 31, 2008**
	(unaudited)	**(Note 2)**
Current Assets:		
Cash and cash equivalents	$493,000	$4,328,000
Assets held-for-sale	299,000	299,000
Deferred financing costs, net of accumulated amortization of $238,000 and $213,000, respectively	—	25,000
Prepaid expenses and other current assets	388,000	958,000
Total Current Assets	1,180,000	5,610,000
Property and equipment, net	1,146,000	1,447,000
Other assets	32,000	259,000
TOTAL ASSETS	$2,358,000	$7,316,000
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Secured convertible notes payable, net of unamortized debt discount of zero and $403,000, respectively	$3,000,000	$3,597,000
Accounts payable	326,000	654,000
Accrued expenses and other current liabilities	1,159,000	924,000
Current portion of deferred revenue	266,000	266,000
Current portion of capital lease obligations	51,000	122,000
Total Current Liabilities	4,802,000	5,563,000
Non-current portion of deferred revenue	4,335,000	4,468,000
Non-current portion of capital lease obligations	9,000	26,000
Total Liabilities	9,146,000	10,057,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIENCY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		

Authorized 200,000,000, issued 60,706,374 and 60,692,260 shares at June 30, 2009 and December 31, 2008, respectively	61,000	60,000
Additional paid-in capital	72,186,000	72,034,000
Accumulated deficit	(79,029,000)	(74,829,000)
Less: treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders' Deficiency	(6,788,000)	(2,741,000)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$2,358,000	$7,316,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2009 AND JUNE 30, 2008

(UNAUDITED)

	Three Months Ended		Six Months Ended	
	June 30, 2009	**June 30, 2008**	**June 30, 2009**	**June 30, 2008**
License Fees and Milestone Fees Earned	$67,000	$ 51,000	$ 133,000	$154,000
Research and Development Expenses	624,000	1,323,000	1,450,000	2,446,000
Consulting, Selling, General and Administrative Expenses	936,000	1,322,000	2,194,000	2,309,000
Loss on Assets Held-for-Sale		342,000		342,000
Total Expenses	1,560,000	2,987,000	3,644,000	5,097,000
Loss From Operations	(1,493,000)	(2,936,000)	(3,511,000)	(4,943,000)
Other Income / (Expense)	(59,000)	—	301,000	—
Interest Expense	(150,000)	(294,000)	(636,000)	(294,000)
Interest Income	1,000	28,000	6,000	63,000
Net Loss	$(1,701,000)	$ (3,202,000)	$ (3,840,000)	$(5,174,000)
Basic and Diluted Loss Per Common Share	$(0.03)	$ (0.05)	$ (0.06)	$(0.09)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	60,081,374	59,592,260	59,987,277	59,592,260

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIENCY

FOR THE SIX MONTHS ENDED JUNE 30, 2009

(UNAUDITED)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Deficiency
	Shares	Amount				
BALANCE, December 31, 2008	60,692,260	$ 60,000	$ 72,034,000	$ (74,829,000)	$ (6,000)	$ (2,741,000)
Share-based compensation expense			153,000			153,000
Cumulative effect for the adoption of EITF 07-05				(360,000)		(360,000)
Restricted stock cancelled	(475,000)					
Cashless exercise of warrants	489,114	1,000	(1,000)			
Net loss				(3,840,000)		(3,840,000)
BALANCE, June 30, 2009	60,706,374	$ 61,000	$ 72,186,000	$(79,029,000)	$(6,000)	$(6,788,000)

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND JUNE 30, 2008

(UNAUDITED)

	Six Months Ended	
	June 30, 2009	**June 30, 2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,840,000)	$ (5,174,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	153,000	416,000
Expiration of warrants	(360,000)	
Amortization of debt discount and deferred financing fees	428,000	249,000
Depreciation and amortization	201,000	275,000
Loss on disposition of fixed assets	59,000	342,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	570,000	443,000
Other assets	227,000	75,000
Accounts payable	(328,000)	(1,016,000)
Accrued expenses and other current liabilities	235,000	(1,280,000)
Deferred revenue	(133,000)	2,921,000
Net cash used in operating activities	(2,788,000)	(2,749,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	41,000	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible notes	—	1,475,000
Deferred financing costs	—	(195,000)
Payments of convertible note obligation	(1,000,000)	—
Payments of capital lease obligations	(88,000)	(95,000)
Net cash (used in) provided by financing activities	(1,088,000)	1,185,000
DECREASE IN CASH AND CASH EQUIVALENTS	(3,835,000)	(1,564,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,328,000	6,384,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 493,000	$ 4,820,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Warrants – discount and beneficial conversion feature	$ —	1,210,000

See accompanying notes to condensed financial statements.

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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, 2008 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, 2008, 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, 2008, 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 $3,840,000 and $5,174,000 and negative cash flows from operating activities of $2,788,000 and $2,749,000 for the six months ended June 30, 2009 and June 30, 2008, respectively. As of June 30, 2009, the Company had negative working capital of $3,622,000 and cash and cash equivalents of $493,000. 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 of 2007 and continuing through the current date, 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 matured on November 30, 2008 and, in the Subsequent Closing, matured 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 did not 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. The convertible notes are secured by all of the assets of the Company, other than certain excluded assets. On April 29, 2009, the Company remitted $1,000,000 to ProQuest Investments and related entities against the $4,000,000 of convertible notes issued during 2008.

On July 16, 2009, the Company received approval from the NYSE AMEX to issue up to 12,000,000 shares over the next twelve (12) months. On July 17, 2009, the Company executed an initial closing with Seaside 88, LP receiving approximately $114,000 in gross proceeds for issuance of 500,000 shares. The Company has entered into an agreement with Seaside 88, LP to purchase common shares in a series of closings every two weeks in the amount of 500,000 shares each for a total of up to 26 purchases.

At the Company's current level of spending, which excludes any product development efforts, assuming that ProQuest does not convert its notes into common stock or demand payment under the notes issued in the Initial Closing, and assuming that 12,000,000 shares are issued in accordance with the common stock purchase agreement at the current floor price with Seaside 88 LLP, the Company estimates that it will have sufficient cash on hand to fund operations through June 2010.

The Company may also determine that it is appropriate to increase development activities on its product candidate pipeline. 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 2010. The Company may choose to raise additional capital in 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 and continuing downturn in the economy, uncertainty in the financial community, and the Company's current cash position, there can be no assurance that additional 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, 2008, 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 and any additional potential cash inflows that may be received during 2009 will improve its ability to continue its operations as a going concern. Continued operations are dependent on the Company's ability to complete product licensing agreements, equity or debt financing 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 Amex LLC (formally known as the American Stock Exchange) indicating that the Company is not in compliance with certain of the NYSE Amex LLC continued listing standards. Specifically, the NYSE Amex LLC has notified the Company that it is not in compliance with Section 1003(a)(iii) of the NYSE Amex LLC 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 Amex LLC 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 Amex LLC, 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 Amex LLC listing, the Company was required to submit a plan by June 13, 2008, advising the NYSE Amex LLC 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 Amex LLC that it intended to submit such a plan, and did so on June 12, 2008.

On July 30, 2008, NYSE Amex LLC notified the Company that the NYSE Amex LLC 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 Amex LLC, 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 Amex LLC is continuing the Company's listing pursuant to an extension, subject to certain conditions.

In addition, as of June 30, 2009, the Company is no longer in compliance with Section 1003(a)(ii) of the NYSE Amex LLC 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 Amex LLC 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 Amex LLC 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). On April 30, 2009, the Company received a letter from NYSE, Amex LLC that the Company's listing on the exchange continues to be extended to the targeted date of November 16, 2009.

The Company will be subject to periodic review by the NYSE Amex LLC during the plan periods and must continue to provide the NYSE Amex LLC 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 Amex LLC.

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 Amex LLC'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 Amex LLC 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, Chief Executive Officer and Interim Chief Financial 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 Amex LLC, 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 was 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 was 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. On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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 $333,000 in net book value of fixed assets as of June 30, 2009, on which $60,000 of capital lease obligations exist at June 30, 2009); (ii) the assets marked as "Assets held for sale" on its balance sheets as of December 31, 2008 and June 30, 2009, which represented assets associated with our NitroMist™ product which is currently being targeted for sale, the amount for which was $299,000 as of June 30, 2009; and (iii) the assets marked as "other assets" on its balance sheets as of June 30, 2009 and December 31, 2008, which represented restricted cash held as security for its letters of credit and leased assets, the amount for which was $32,000 and $259,000 respectively.

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 Securities Exchange Commission ("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. On May 5, 2009, the Company received notice from the SEC approving the effective registration of 8,934,075 shares. An additional 9,044,649 shares remain unregistered.

The Company has 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, the Company may be subject to liability to pay liquidated damages.

With respect to the subsequent closing of the 2008 private placement, we agreed to file a registration statement with the SEC to register the resale of 17,978,724 shares of common stock issuable pursuant to the 2008 private placement, referred to herein as the subsequent registrable shares, within 30 days of the related closing. Also, we agreed to respond to all SEC comment letters as promptly as reasonably possible and to use our best efforts to have the registration statement declared effective within 90 days of the related closing. However, we were unable to register 9,044,649 of the subsequent registrable shares in accordance with the rules and regulations of the SEC. Therefore, we have filed the registration statement with the SEC to register the resale of 8,934,075 subsequent registrable shares issuable pursuant to the 2008 private placement. The registration of these shares became effective on May 5, 2009. In connection with our reduction of subsequent registrable shares being registered on the registration statement, we have agreed with the purchasers to pay, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by the purchasers for the shares that we are not able to register for resale under the registration statement. Such liquidated damages equal $12,703 for each 30 day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by the purchasers, or $127,030, which the Company has recorded as a liability. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note).

On May 5, 2009, the Company received notice from the Securities Exchange Commission approving the effective registration of 8,934,075 shares.

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 six months ended June 30, 2009, the Company has recorded additional interest expense of $403,000, related to the amortization of the debt discount for the Initial Closing.

The balance of the convertible debt as of June 30, 2009 is summarized as follows:

Face amount	$ 3,000,000
Total debt discount and beneficial conversion feature	1,900,000
Amortization of debt discount and beneficial conversion feature	1,900,000
Net unamortized debt discount and beneficial conversion feature	-
Net debt recorded at June 30, 2009	$ 3,000,000

On April 29, 2009, the Company remitted $1,000,000 to ProQuest Investments and related entities against the $4,000,000 of convertible notes issued during 2008.

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Related to the issuance of the initial offer, the Company paid debt finance costs totaling $238,000, which were capitalized as deferred financing costs. These costs were amortized into interest expense using straight line method, which result did not differ materially from the effective interest rate method. For the six months ended June 30, 2009, the Company had recorded expense of $25,000 related to the amortization of the deferred financing costs.

The Company has accounted 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. As of June 30, 2009, the balance in this account is zero.

NOTE 4 – CASH EQUIVALENTS

Cash equivalents include certificates of deposit and money market instruments with 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.

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 June 30, 2009 and June 30, 2008, there were 25,700,000 and 43,300,000 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 June 30, 2009, 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 June 30, 2009, there were approximately 3,400,000 shares available for issuance under the Plans.

The Company adopted the provisions of SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. SFAS 123(R) 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 123(R) 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 six months ended June 30, 2009 is as follows:

Options	Shares (000)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2008	5,467	$ 1.59	5.4	—
Grants	2,163	0.34	—	
Exercises	—	—	—	
Forfeitures	(2,007)	1.45	—	
Outstanding at June 30, 2009	5,623	$ 1.15	4.5	$ —
Vested and expected to vest at June 30, 2009	5,503	$ 1.16	4.5	$ —
Exercisable at June 30, 2009	3,241	$ 1.46	3.8	$

The Company recorded share-based compensation expense using the fair value method required by SFAS 123(R) of approximately $4,000 or $0.000 per share, and $152,000 or $0.003 per share, for the three and six months ended June 30, 2009, respectively, and $199,000 or 0.003 per share, and $416,000 or $0.010 per share, for the three and six months ended June 30, 2008, respectively. All such amounts are included in the Company's net loss for each period. Share-based compensation expense for the current quarter and year-to-date was reduced due to headcount reductions taken during the second quarter of 2009.

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 $5.0 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 $5.0 million (or $10.0 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 $20.0 million (or $20.0 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 $5.0 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 $5.0 million (or $10.0 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. However, the Company did not achieve such non-dilutive financings on or before December 31, 2008 and, as a result, the additional shares of restricted common stock were not granted to Mr. Ratoff.

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A summary of the status of the Company's non-vested restricted common stock as of June 30, 2009 and changes during the six months ended June 30, 2009 is presented below:

Non-Vested Restricted Common Stock	Shares (000)	Weighted Average Grant-Date Fair Value
January 1, 2009	1,133	$0.51
Cancellations	(475)	$0.47
June 30, 2009	658	$0.53

As of June 30, 2009, unamortized share-based compensation expense of $0.9 million remains to be recognized, which is comprised of $0.4 million related to non-performance based stock options to be recognized over a weighted average period of 1.2 years, $0.2 million related to restricted stock to be recognized over a weighted average period of 1.6 years, and $0.3 million 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		Six Months Ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
Expected volatility	—	—	85%	—
Dividend yield	—	—	0%	—
Expected term (years)	—	—	3.06%	—
Risk-free interest rate	—	—	1.7%	—

The above table represents the weighted-average assumptions for all stock options granted during the three and six months ended June 30, 2009 and June 30, 2008. The Company did not grant any stock options during the three months ended June 30, 2009, however granted 2.2 million stock options to employees and directors, including 800,000 performance-based stock options during the six months ended June 30, 2009, including performance-based options. The Company used the following weighed average assumptions in determining the fair value for such performance-based options granted in 2009: expected volatility of 85%; dividend yield of 0%; expected term of 3.06 years; and risk-free interest rate of 1.7%.

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 $0.34 during the six months ended June 30, 2009. No options were exercised during the three months ended June 30, 2009 or during the three months ended June 30, 2008.

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 months ended June 30, 2009, the Company recognized $38,462 of income related to this contract.

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.

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. 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 March 31, 2009. 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.

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 June 30, 2009 is $17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff $52,500 and $105,000 for the three and six months ended June 30, 2009, respectively, and $52,500 and $105,000 for the three and six months ended June 30, 2008, respectively, for services rendered during such periods. Additionally, Mr. Ratoff is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments.

Other License and Development Agreements

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.

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NOTE 8 – OTHER INCOME / (EXPENSE)

In June 2008, the FASB issued EITF 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock." EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, "Accounting For Derivative Instruments and Hedging Activities" and/or EITF 00-19, "Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock." EITF 07-05 is effective as of the beginning of our 2009 fiscal year. The adoption of EITF 07-05 resulted in an adjustment to opening accumulated deficit in the amount of $360,000 to account for the reclassification of the fair value of certain outstanding warrants from stockholders' deficiency to liability. The warrants affected by the adoption of EITF 07-05 expired during the first quarter of 2009 and, as a result, the fair value of the warrant liability was reduced to zero as of the end of the reporting period. Also included in Other Income / (Expense) is a loss on the sale of fixed assets of $59,000.

NOTE 9 - NEW ACCOUNTING PRONOUNCEMENTS

In April 2009, the FASB amended FASB Statement No, 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods and APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods effective for interim reporting periods ending after June 15, 2009. The adoption of FASB 107-1 and APB 28-1 did not have a material impact on our results from operations or on our financial condition. Financial instruments include cash and cash equivalents, short-term investments, and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

In May 2009, the FASB issued SFAS No. 165, "Subsequent Events" ("SFAS 165"). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 became effective for us beginning with the interim period ended June 30, 2009, and did not have a material impact on our results from operations or on our financial condition. We evaluated subsequent events through the time of filing these financial statements with the SEC on August 12, 2009.

NOTE 10 – SUBSEQUENT EVENTS

On July 17, 2009, the Company had its initial closing of the Offering pursuant to which Seaside purchased 500,000 shares of the Company's Common Stock at a price per share of $0.23 having an aggregate value of approximately $114,000 and net proceeds of approximately $91,000 after deducting direct expenses. Additionally on July 31, 2009, the Company had another closing of the Offering of which Seaside purchased 500,000 shares of the Company's at a price per share of $0.22 having an aggregate value of approximately $112,000 and net proceeds of approximately $107,000 after deducting direct expenses.

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 Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q, 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 69 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 June 30, 2009 of $79,029,000, as compared to $74,829,000 as of December 31, 2008. We have had negative cash flow from operating activities of $2,788,000 and $2,749,000 for the six months ended June 30, 2009 and 2008, respectively. As of June 30, 2009, we had negative working capital of $3,622,000, as compared to $47,000 as of December 31, 2008, representing a net decrease in working capital of approximately $3,575,000.

Since the fourth quarter 2007 and continuing throughout 2009, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products, 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, collectively referred to herein as the 2008 Financing. The convertible notes issued in the initial closing matured on November 30, 2008 and, in the subsequent closing, matured 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 did not 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.

We are seeking to raise additional capital in 2009 to fund future development activities through a license agreement or by taking advantage of other strategic opportunities. These opportunities could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. Our ability to fund operations is also dependent on whether ProQuest Investments, or ProQuest, to which we have $3.0 million of outstanding secured convertible notes relating to fiscal 2008, now consist of $.5 million of notes issued in the initial closing on May 30, 2008, the Initial Closing Notes, and $2.5 million of notes issued in the subsequent closing on October 17, 2008, the Subsequent Closing Notes, demands payment under such notes. This reflects $1.0 million payment made to ProQuest Investments on April 29, 2009. Given our current level of spending, if ProQuest demands payment under the Initial Closing Notes and the Subsequent Closing Notes, we will not be able to repay the notes in full, unless we are successful prior to that time in securing funds through new strategic partnerships and/or the sale of common stock or other securities. However, if ProQuest demands payment under the Initial Closing Notes and under the Subsequent Closing notes and we are not successful in securing new funds, we will not have sufficient cash on hand to fund operations. If ProQuest fully converts the Initial Closing Notes and Subsequent Closing notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through third quarter 2009.

In addition, we have agreed to pay ProQuest, as partial liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note).

Given the recent downturn in the economy, uncertainty in the financial community, and our current cash position, 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, 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. 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, the recent Common Stock Purchase Agreement (the "Agreement") with Seaside 88, LP ("Seaside") relating to the offering and sale of a total of up to 13,000,000 shares (the “Shares”) of the Company’s common stock, $0.001 par value per share (the "Common Stock") (the Offering”) and any additional potential cash inflows that may be received during 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 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 Amex LLC indicating that we were not in compliance with certain of the NYSE Amex LLC continued listing standards. Specifically, the NYSE Amex LLC has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex LLC 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 Amex LLC 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 Amex LLC, 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 Amex LLC listing, we were required to submit a plan by June 13, 2008, advising the NYSE Amex LLC 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 Amex LLC that we intended to submit such a plan, and did so on June 12, 2008.

On July 30, 2008, NYSE Amex LLC notified us that the NYSE Amex LLC 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 Amex LLC, 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 were November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Amex LLC was continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of June 30, 2009, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Amex LLC Company Guide with stockholders’ equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years; and Section 1003(a)(i) of the NYSE Amex LLC Company Guide with stockholders’ equity of less than $2,000,000 and losses from continuing operations and net losses in two of our three most recent fiscal years. However, as previously noted, the plan that we submitted to the NYSE Amex LLC 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).

On January 23, 2009, we were notified by the NYSE Amex LLC that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex LLC Company Guide. Our deadline to regain compliance with Section 1003(a)(i), (ii) and (iii) remains November 16, 2009. On April 30, 2009, the Company received a letter from NYSE Amex LLC that the Company’s listing on the exchange continues to be extended to the targeted date of November 16, 2009.

We will be subject to periodic review by the NYSE Amex LLC during the plan periods and must continue to provide the NYSE Amex LLC 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 Amex LLC.

There can be no assurance that we will be able to make progress consistent with our plan to regain compliance with NYSE Amex LLC'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 Amex LLC 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 six months ended June 30, 2009, and additionally through the date of filing of this Quarterly Report on Form 10-Q, include the following:

Other

- Announced that we received a notification from NYSE Amex LLC that we were not in compliance with certain of the NYSE Amex LLC continued listing standards. On June 12, 2008, we submitted a plan of compliance to the NYSE Amex LLC for review. On July 30, 2008, NYSE Amex LLC 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. On January 23, 2009, the NYSE Amex LLC notified us that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex LLC Company Guide. The NYSE Amex LLC is continuing our listing pursuant to an extension, subject to certain conditions.

- Announced that Michael E. Spicer resigned as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. Our Board of Directors appointed Deni M. Zodda, our Chief Business Officer, to serve as Interim Chief Financial Officer, Principal Financial Officer and Corporate Secretary, effective April 1, 2009. We also hired Joseph M. Warusz as a consultant to serve as Principal Accounting Officer, effective April 1, 2009.

- On April 28, 2009, the Company executed a lease amendment modifying certain terms to the existing lease. The amendment converts the lease term to month to month commencing on July 1, 2009 with a provision that either party may terminate the lease upon thirty days written notice. The Company has released the lease escrow of $226,000 to the landlord in order to satisfy rent payments through June 30, 2009.

- On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

- Effective April 30, 2009, Deni M. Zodda, Ph.D., Chief Business Officer, Interim Chief Financial Officer and Corporate Secretary of the Company, agreed to leave the Company resulting from a reorganization of the executive team. Mr. Zodda has entered into a Separation, Consulting and General Release Agreement under which he will receive a one-time fee of $137,500 and will provide the Company with certain consulting services through October 31, 2009. Steven B. Ratoff, the Company’s Chairman, Interim President and Chief Executive Officer, has been appointed its Interim Chief Financial Officer.

- On June 26, 2009, the Company entered into a Common Stock Purchase Agreement (the "Agreement") with Seaside 88, LP ("Seaside") relating to the offering and sale of a total of up to 13,000,000 shares (the “Shares”) of the Company’s common stock, $0.001 par value per share (the "Common Stock") (the Offering”). The Agreement requires the Company to issue and sell, and Seaside to purchase, 500,000 shares of the Company’s Common Stock once every two (2) weeks, subject to the satisfaction of customary closing conditions, for twenty-six (26) closings over a fifty-two (52) week period.

- On July 17, 2009, the Company had its initial closing of the Offering pursuant to which Seaside purchased 500,000 shares of the Company’s Common Stock at a price per share of $0.23 having an aggregate value of approximately $114,000. The Company received net proceeds of approximately $91,000 after deducting direct expenses related to the initial close of approximately $23,000. Additionally, on July 31, 2009, the Company had another closing of the Offering of which Seaside purchased 500,000 shares of the Company’s common stock at a price per share of $0.22 having an aggregate value of approximately $112,000 and net proceeds of approximately $107,000 after deducting direct

expenses.

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Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the 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 spend significant amounts on the development of our product candidates and we expect our costs to increase if we restart programs 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 Products				
NitroMist™	nitroglycerin	Angina Pectoris	FDA Approved	-
Zolpimist™	zolpidem	Insomnia	FDA Approved	-
Product Candidates				
Zensana™	ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.
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. Our former contract manufacturer for NitroMist™, INyX Pharma, filed for protection under the Chapter 11 bankruptcy laws in 2007, and ceased operations at its facility in Puerto Rico where our product was to be manufactured during 2008. As a result, we selected an alternative contract manufacturer, DPT Laboratories, and are in the process of transferring manufacturing operations to DPT. 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. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist™ for the short-term treatment of insomnia. We are currently investigating strategic partners for this product.

Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GlaxoSmithKline, or 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 had previously announced that it expected to complete clinical development on the revised formulation of Zensana™ during 2008, and expected 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. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™.

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.

On May 19, 2008, we entered into an agreement with BioAlliance Pharma S.A., whereby BioAlliance acquired the European rights for our ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are 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. We anticipate collaborating with BioAlliance in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product.

Sumatriptan oral spray (NVD-201). Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by 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).