NOVADEL PHARMA INC
Form S-3/A
April 06, 2009

As filed with the Securities and Exchange Commission on April 6, 2009

Registration Statement No. 333-155345

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 2 TO

FORM S-3

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NovaDel Pharma Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	2834	22-2407152
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code)	(I.R.S. Employer Identification No.)

25 Minneakoning Road
Flemington, NJ 08822
(908) 782-3431
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Steven B. Ratoff
Interim President and Chief Executive Officer

NovaDel Pharma Inc.
25 Minneakoning Road
Flemington, NJ 08822
(908) 782-3431
(Name, address, including zip code, and telephone number including area code, of agents for service)

Copies to:
Emilio Ragosa, Esq.
Morgan, Lewis & Bockius, LLP, 502 Carnegie Center, Princeton, New Jersey 08540 (609) 919-6600

Approximate date of commencement of proposed sale to public: From time to time or at one time after this Registration Statement becomes effective in light of market conditions and other factors.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 (the Securities Act), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. 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 definitions of smaller reporting company, accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

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

CALCULATION OF REGISTRATION FEE

Title of Shares To Be Registered	Amount To Be Registered	Amount Of Registration Fee
Common Stock, $0.001 par value	8,934,075(1)	$116.00(2)

(1) Represents 8,934,075 shares of the registrant s common stock underlying convertible notes at a conversion price of $0.235 per share. Pursuant to Rule 416 of the Securities Act of 1933, as amended, this registration statement shall also cover any additional shares of common stock by reason of any stock dividend, stock split, recapitalization or other similar transaction or to cover such additional shares as may hereinafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments, effected without the registrant s receipt of consideration, which results in an increase in the number of the outstanding shares of registrant s common stock.

(2) A registration fee of $136.00 was previously paid in connection with the initial filing of this Registration Statement on Form S-3 (File No. 333-155345), which was filed by the Company on November 13, 2008.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT

SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

The information in this prospectus is not complete and may be changed or amended. The selling security holders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated April 6, 2009

Prospectus

SHARES OF COMMON STOCK

This prospectus covers resales by certain of our stockholders of up to 8,934,075 shares of our common stock, par value $0.001 per share, for their own accounts. Such stockholders are referred to throughout this prospectus as selling security holders.

In this prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms NovaDel , the Company , we , us , and our r and relate to NovaDel Pharma Inc. The selling security holders who wish to sell their shares of our common stock may offer and sell such shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of the shares of common stock owned by the selling security holders but we will receive funds from the exercise of their warrants, if at all. However, the warrants contain provisions for cashless exercise, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders. Any such proceeds will be used primarily for increased or additional research and development and general working capital. One should read this prospectus and any amendment or supplement hereto together with additional information described under the heading Where You Can Find Available Information .

Our common stock is listed for trading on the NYSE Amex LLC (formerly known as the American Stock Exchange), or NYSE Amex, under the symbol NVD. On March 20, 2009, the closing sales price for our common stock on the NYSE Amex was $0.29 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE RISK FACTORS SECTION BEGINNING ON PAGE 24 BEFORE YOU DECIDE TO PURCHASE ANY SHARES OF OUR COMMON STOCK.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____, 2009

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PROSPECTUS SUMMARY

About This Prospectus

This prospectus is a part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission, referred to herein as the SEC, to register 8,934,075 shares of our common stock. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Accordingly, you should refer to the registration statement and its exhibits for further information about us and our common stock. Copies of the registration statement and its exhibits are on file with the SEC. Statements contained in this prospectus concerning the documents we have filed with the SEC are not intended to be comprehensive, and in each instance we refer you to the copy of the actual document filed as an exhibit to the registration statement or otherwise filed with the SEC.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling security holders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

About the Financing

On May 6, 2008, we 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 us 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.

On May 30, 2008, we 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 (formerly known as the American Stock Exchange), referred to herein as NYSE Amex, and satisfaction of customary closing conditions. The 5,000,000 shares, along with the prior securities owned by the Purchasers, represented 19.8% of our outstanding common stock upon execution of the Securities Purchase Agreement. At our Annual Stockholders Meeting on September 8, 2008, we 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, we closed the Subsequent Closing, for gross proceeds of $2,525,000.

In the Initial Closing, we issued the convertible notes, which convert into our 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 our common stock, with an exercise price of $0.369 per share. The maturity date of the convertible notes issued in the Initial Closing is November 30, 2008. In addition, the documents provide that the warrants issuable at the Initial Closing were subject to a cap on the number of shares of common stock that can be issued upon the exercise of the warrants to a maximum of 19.99% of our outstanding common stock at the time of exercise unless we received stockholder approval in accordance with NYSE Amex rules. We sought and received such stockholder approval at our Annual Stockholders Meeting on September 8, 2008.

In the Subsequent Closing, we issued the convertible notes, which convert into 10,744,681 shares of our 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 our common stock, with an exercise price of $0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing is April 17, 2009.

The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10% per annum. 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 our common stock. If we pay interest in common stock, the stock will be valued at the related conversion price for such convertible note, and we will record interest expense based on the fair value of the common stock.

At our option, we 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 we 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.

Our obligations under the convertible notes are secured by all of our assets and intellectual property, with the exception of certain excluded assets, as evidenced by the Security and Pledge Agreement, executed on May 6, 2008. The excluded assets are (i) those assets that are the subject of our existing capital leases (approximately $419,000 in net book value of fixed assets as of December 31, 2008, on which $148,000 of capital lease obligations exist at December 31, 2008); (ii) the assets marked as Assets held for sale on our balance sheets as of December 31, 2007 and December 31, 2008, which represented assets associated with our NitroMist product which is currently being targeted for sale, the amount for which was $299,000 as of December 31, 2008; and (iii) the assets marked as Other Assets on our balance sheets as of December 31, 2007 and December 31, 2008, which represented restricted cash held as security for our letters of credit and leased assets, the amount for which was $259,000 as of December 31, 2008.

In association with the Closings, the Purchasers will be issued warrants to purchase our common stock, exercisable six months and one day from the date of issuance until their expiration on the date that is five years from the date of issuance. The warrants issued to the Purchasers in the Initial Closing represent the right to purchase the aggregate of 3,000,000 shares of our common stock, with an exercise price of $0.369 per share. The warrants issued to the Purchasers in the Subsequent Closing represent the right to purchase the aggregate of 6,446,809 shares of our common stock, with an exercise price of $0.294 per share. The warrants provide a right of cashless exercise if, at the time of exercise, there is no effective registration statement registering the resale of the shares underlying the warrants.

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.

We filed an initial registration statement with the SEC to register the resale of common stock issuable in connection with the Initial Closing (excluding interest shares), referred to herein as the initial registrable shares, on June 26, 2008, which registration statement became effective as of July 16, 2008. We filed this registration statement with the SEC within 30 days of the date of the Subsequent Closing to register the resale of common stock issuable upon conversion of the convertible notes issued in connection with the Subsequent Closing, referred to herein as the subsequent registrable shares and together with the initial registrable shares, the registrable shares. These registration rights will cease once the registrable shares are eligible for sale by the Purchasers without restriction under Rule 144. Upon certain events, we have agreed to pay as liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the Purchasers for any convertible notes then held by the Purchasers, but these payments may not exceed 10% of the aggregate purchase price paid by the Purchasers.

The 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.

The gross proceeds of the sale will be up to $4,000,000, of which $1,475,000 was funded at the Initial Closing and $2,525,000 was funded at the Subsequent Closing.

About the Initial Closing

In the Initial Closing the Purchasers received $1,475,000 of convertible notes and warrants to purchase 3,000,000 shares of our common stock. The following discussion sets forth the dilutive effect of the Initial Closing on our common stock. Under the terms of the Securities Purchase Agreement, the warrants are subject to a cap of 19.99%, which prevents the exercise of the warrants if such exercise would cause the holder to own more than 19.99% of the total outstanding shares of our common stock at the time of exercise. Furthermore, the convertible notes provide that we can pay interest, at the holder s option, in shares of our common stock, referred to herein as the interest shares provision. The following table illustrates the maximum number of shares that the Purchasers may receive in the Initial Closing.

Investor	Total Number of Shares Underlying Convertible Notes in the Initial Closing(1)	Total Number of Shares Underlying Warrants in the Initial Closing(2)	Estimated Number of Interest Shares(3)	Maximum Number of Shares that may be Issued Pursuant to the Initial Closing(4)
ProQuest Investments II Advisor Fund L. P.	24,251	14,551	1,213	40,015
ProQuest Investments II, L.P.	1,007,365	604,419	50,368	1,662,152
ProQuest Investments III, L.P.	3,968,384	2,381,030	198,419	6,547,833
Total:	**5,000,000**	**3,000,000**	**250,000**	**8,250,000**

(1) This represents the number of shares issuable upon conversion of the convertible notes at the conversion price of $0.295 per share. This amount does not include interest shares.

(2) This represents the number of shares issuable upon exercise of the warrants at the exercise price of $0.369 per share.

(3) This represents the estimated amount of interest shares that may be issued upon conversion of the convertible notes. The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10%. We may, at the holder s option, pay interest in cash or common stock at maturity. If we pay interest in common stock, the stock will be valued at the conversion price of $0.295 per share, and we will record interest expense based on the fair value of the common stock.

(4) This represents the maximum number of shares that may be issued to the Purchasers.

The following table illustrates the beneficial ownership of the Purchasers upon full exercise of the warrants and full conversion of the interest shares in the Initial Closing:

Investor (1)	Beneficial Ownership of Investor at Initial Closing (2)		Beneficial Ownership of Investor upon full exercise of warrants and full conversion of interest shares (3)	
	Number	Percentage	Number	Percentage
ProQuest Investments (4)	13,474,832	19.8%	16,724,832	23.5%

(1) For the purposes of the foregoing table, the calculation of beneficial ownership assumes that the Subsequent Closing has not occurred.

(2) Ownership is based upon the number of outstanding shares of common stock as of June 20, 2008 and assuming the consummation of the Initial Closing. The beneficial ownership calculated herein does not include the warrants issued pursuant to the Initial Closing or the potential interest shares from the Initial Closing because such warrants may not be exercised and such interest shares may not be issued, if such exercise or issuance would cause the holders to beneficially own more than 19.99% of the total shares outstanding at the time of such exercise or issuance; however, it does include the shares of common stock underlying the convertible notes because such convertible notes may be fully converted at any time.

(3) Ownership is based upon the sum of (a) the number of outstanding shares of common stock as of June 20, 2008, (b) the total number of warrants issued prior to the financing, assuming full exercise at the related exercise price and (c) the total number of shares underlying all convertible notes and warrants issued, and to be issued, in the financing, assuming full conversion at the related conversion price and full exercise at the related exercise price, and including interest shares and other additional shares issuable pursuant to potential adjustments to the exercise and conversion prices.

(4) For the purposes of this registration statement, the numerical information contained in this table consists of the aggregate beneficial ownership of each of ProQuest Investments II, L.P., ProQuest Investments III, L.P. and ProQuest Investments II Advisors Fund, L.P.

The stockholders equity per share of our common stock as of March 31, 2008 and assuming the Initial Closing has occurred was approximately $2.4 million, or approximately $0.040 per share, based on 60,692,260 shares of our common stock outstanding. Stockholders equity per share represents the amount of our assets, less our liabilities, divided by the total number of shares of our common stock outstanding and the consummation of the Initial Closing. Dilution in stockholders equity per share to new investors represents the difference between the amount per share paid by the Purchasers and the stockholders equity per share of our common stock immediately afterwards. Without taking into account any other changes in stockholders equity per share after March 31, 2008 and the consummation of the Initial Closing, other than the potential exercise of the warrants for 3,000,000 shares of common stock and the potential interest shares of 250,000 shares of common stock, our stockholders equity would have increased slightly to approximately $2.8 million, or approximately $0.043 per share, based on 65,692,260 shares of our common stock outstanding. This represents an immaterial increase in stockholders equity per share to existing stockholders in the Initial Closing, due to the inclusion of approximately $400,000 in stockholders equity related to the Initial Closing. Assuming the potential exercise of warrants for 3,000,000 shares of common stock and the potential interest shares of 250,000 shares of common stock, our stockholders equity would remain at approximately $2.8 million, or approximately $0.040 per share, based on 68,942,260 shares of our common stock outstanding. The following table illustrates this per share dilution:

Stockholders equity per share as of March 31, 2008 and assuming the Initial Closing has not occurred	$0.040
Stockholders equity per share as of March 31, 2008 and assuming the Initial Closing has occurred	$0.043
As adjusted stockholders equity per share after approval of the Interest Shares and Warrant Shares	$0.040
Dilution per share to Purchasers.	$0.003

These calculations exclude shares of common stock issuable upon exercise of options, warrants and other rights, and the effect of shares of common stock issued, except as indicated above for ProQuest Investments, since June 20, 2008.

The following table sets forth the dilutive effect on the beneficial ownership of the existing stockholders (other than ProQuest Investments) upon full exercise of the warrants and full conversion of the interest shares in the Initial Closing.

	Beneficial Ownership of Existing Stockholders at Initial Closing (3)		**Beneficial Ownership of Existing Stockholders upon full exercise of warrants and full conversion of interest shares (4)**	
	Number	**Percentage**	**Number**	**Percentage**
Existing Stockholders (other than ProQuest Investments) (1)(2):	80,953,626	85.7%	80,953,626	82.9%

(1) For the purposes of the foregoing table, the calculation of beneficial ownership assumes that the Subsequent Closing has not occurred.

(2) For purposes of clarification, the percentage represented by the Existing Stockholders excludes any current and prior ownership of ProQuest Investments, but includes all options, warrants and other convertible securities held by the Existing Stockholders exercisable within 60 days of June 20, 2008.

(3) Ownership is based upon the number of outstanding shares of common stock as of June 20, 2008 and includes all options, warrants and other convertible securities held by the Existing Stockholders exercisable within 60 days of June 20, 2008. This calculation also assumes full conversion of the convertible notes in the Initial Closing at the related conversion price.

(4) Ownership is based on the sum of (a) the number of outstanding shares of common stock as of June 20, 2008, (b) the total number of options, warrants and other convertible securities exercisable within 60 days of June 20, 2008, assuming full conversion or full exercise at the related conversion price or exercise price, and (c) the total number of shares underlying all convertible notes and warrants issued, and to be issued, in the financing, assuming full conversion at the related conversion price and full exercise at the related exercise price, and including interest shares assuming issuance at the related conversion price.

About the Subsequent Closing

In the Subsequent Closing, the Purchasers received $2,525,000 of convertible notes and warrants to purchase 6,446,809 shares of our common stock. The following discussion sets forth the dilutive effect of the Subsequent Closing on our common stock. Under the terms of the Securities Purchase Agreement, the convertible notes provide that we can pay interest, at the holder s option, in shares of our common stock, referred to herein as the interest shares provision. The following table illustrates the maximum number of shares that the Purchasers may receive in the Subsequent Closing.

Investor	Total Number of Shares Underlying Convertible Notes in the Subsequent Closing(1)	Total Number of Shares Underlying Warrants in the Subsequent Closing(2)	Estimated Number of Interest Shares(3)	Maximum Number of Shares that may be Issued Pursuant to the Subsequent Closing(4)
ProQuest Investments II Advisor Fund L. P.	52,114	31,268	2,606	85,988
ProQuest Investments II, L.P.	2,164,764	1,298,858	108,238	3,571,860
ProQuest Investments III, L.P.	8,527,803	5,116,683	426,390	14,070,876
Total:	**10,744,681**	**6,446,809**	**537,234**	**17,728,724**

(1) This represents the number of shares issuable upon conversion of the convertible notes at the conversion price of $0.235 per share. This amount does not include interest shares.

(2) This represents the number of shares issuable upon exercise of the warrants at the exercise price of $0.294 per share.

(3) This represents the estimated amount of interest shares that may be issued upon conversion of the convertible notes. The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10%. We may, at the holder s option, pay interest in cash or common stock at maturity. If we pay interest in common stock, the stock will be valued at the conversion price of $0.235 per share, and we will record interest expense based on the fair value of the common stock.

(4) This represents the maximum number of shares that may be issued to the Purchasers in connection with the Subsequent Closing.

The following table illustrates the beneficial ownership of the Purchasers upon full exercise of the warrants and full conversion of the convertible notes issued in each closing:

Investor	Beneficial Ownership of Investor before the Subsequent Closing (1)		Beneficial Ownership of Investor upon full exercise of warrants and full conversion of convertible notes (2)	
	Number	Percentage	Number	Percentage
ProQuest Investments (3)	16,474,832	23.1%	34,453,556	38.6%

(1) Ownership is based upon the number of outstanding shares of common stock as of March 20, 2009, includes all options, warrants and other convertible securities held by ProQuest Investments exercisable within 60 days of March 20, 2009 and includes all shares of common stock issuable upon conversion of the convertible notes issued in the Initial Closing (excluding interest shares) and upon exercise of the warrants issued in the Initial Closing.

(2) Ownership is based upon the sum of (a) the number of outstanding shares of common stock as of March 20, 2009, (b) the total number of warrants issued prior to the financing, assuming full exercise at the related exercise price and (c) the total number of shares underlying all convertible notes and warrants issued in the Initial Closing and the Subsequent Closing, assuming full conversion at the related conversion

price and full exercise at the related exercise price, and including interest shares and other additional shares issuable pursuant to potential adjustments to the exercise and conversion prices in the Initial Closing and the Subsequent Closing.

(3) For the purposes of this registration statement, the numerical information contained in this table consists of the aggregate beneficial ownership of each of ProQuest Investments II, L.P., ProQuest Investments III, L.P. and ProQuest Investments II Advisors Fund, L.P.

The stockholders equity per share of our common stock as of December 31, 2008 was approximately a deficit of $2.7 million, or approximately ($0.032) per share, based on 86,670,984 shares of our common stock outstanding. Stockholders equity per share represents the amount of our assets, less our liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2008, and including shares underlying all convertible notes and warrants issued in the Initial Closing and the Subsequent Closing, as well as potential interest shares issuable pursuant to the Initial Closing and the Subsequent Closing. Dilution in stockholders equity per share to new investors represents the difference between the amount per share paid by the Purchasers and the stockholders equity per share of our common stock immediately afterwards. Without taking into account any other changes in stockholders equity per share after December 31, 2008 and excluding the consummation of the Subsequent Closing, our stockholders equity would have been a deficit of approximately $3.1 million, or approximately ($0.045) per share, based on 68,692,260 shares of our common stock outstanding, and including shares underlying all convertible notes and warrants in the Initial Closing. The increase in stockholders equity per share to existing stockholders in the Subsequent Closing is due to the inclusion of approximately $350,000 in stockholders equity related to the Subsequent Closing. The following table illustrates this per share dilution:

Stockholders equity per share as of December 31, 2008 and assuming the Subsequent Closing has not occurred	($0.045)
Stockholders equity per share as of December 31, 2008 and assuming the Subsequent Closing has occurred	$0.013
Dilution per share to Purchasers.	($0.032)

These calculations exclude shares of common stock issuable upon exercise of options, warrants and other rights, and the effect of shares of common stock issued, except as indicated above for ProQuest Investments, since March 20, 2009.

The following table sets forth the dilutive effect on the beneficial ownership of the existing stockholders (other than ProQuest Investments) upon full exercise of the warrants and full conversion of the convertible notes.

	Beneficial Ownership of Existing Stockholders before Subsequent Closing (2)		**Beneficial Ownership of Existing Stockholders upon full exercise of warrants and full conversion of convertible notes (3)**	
	Number	**Percentage**	**Number**	**Percentage**
Existing Stockholders (other than ProQuest Investments) (1):	70,687,741	81.1%	70,687,741	67.2%

(1) For purposes of clarification, the percentage represented by the Existing Stockholders excludes any current and prior ownership of ProQuest Investments, but includes all options, warrants and other convertible securities held by the Existing Stockholders exercisable within 60 days of March 20, 2009.

(2) Ownership is based upon the number of outstanding shares of common stock as of March 20, 2009 and includes all options, warrants and other convertible securities held by the Existing Stockholders exercisable within 60 days of March 20, 2009. This calculation also assumes full conversion of the convertible notes and full exercise of the warrants issued in the Initial Closing at the related conversion price or exercise price.

(3) Ownership is based on the sum of (a) the number of outstanding shares of common stock as of March 20, 2009, (b) the total number of options, warrants and other convertible securities exercisable within 60 days of March 20, 2009, assuming full conversion or full exercise at the related conversion price or exercise price, and (c) the total number of shares underlying all

convertible notes and warrants issued in the Initial Closing and the Subsequent Closing, assuming full conversion at the related conversion price and full exercise at the related exercise price, and including interest shares assuming issuance at the related conversion price in the Initial Closing and the Subsequent Closing.

About the 8,934,075 shares subject to registration under this Registration Statement

The following table illustrates the value of our common stock underlying the convertible notes and premium to market price that the Purchasers have paid.

Market Price(1)	Conversion Price	Total Shares Underlying Convertible Notes(2)	Total Value of Shares at Market Price(3)	Total Value of Shares at Conversion Price(4)	Total Premium to Market Price(5)
$0.16	$0.235	10,744,681	$1,719,149	$2,525,000	$805,851

(1) Market price per share of our common stock on October 16, 2008 (the closing price prior to the Subsequent Closing).

(2) Total number of shares of common stock underlying the convertible notes assuming full conversion at the related conversion price.

(3) Total market value of shares of common stock underlying the convertible notes assuming full conversion of the convertible notes and based on the market price of the common stock on October 16, 2008.

(4) Total value of shares of common stock underlying the convertible notes assuming full conversion of the convertible notes and based on the fixed conversion price.

(5) Premium to market price calculated by subtracting the result in footnote (3) from the result in footnote (4).

The Purchasers were issued warrants to purchase our common stock, with an expiration date that is five years from the date of issuance. The warrants represent the right to purchase the aggregate of 6,446,809 shares of our common stock, and have an exercise price of $0.294 per share. The warrants provide a right of cashless exercise if, at the time of exercise, there is no effective registration statement registering the resale of the shares underlying the warrants.

The following table illustrates the potential premium of the warrants paid by the Purchasers assuming the Purchasers exercise them on a cash basis.

Market Price(1)	Exercise Price(2)	Total Shares Underlying the Warrants(3)	Total Value of Shares at Market Price(4)	Total Value of Shares at Exercise Price(5)	Total Possible Premium to Market Price(6)
$0.16	$0.294	6,446,809	$1,031,489	$1,895,362	$863,873

(1) Market price per share of our common stock on October 16, 2008.

(2) Warrant exercise price per share of our common stock.

(3) Total number of shares of common stock underlying the warrants assuming full exercise of the warrants.

(4) Total market value of the shares of common stock underlying the warrants assuming full exercise of the warrants based on the market price of the common stock on October 16, 2008.

(5) Total value of shares of common stock underlying the warrants assuming full exercise of the warrants based on the exercise price.

(6) Premium to market price calculated by subtracting the result in footnote (4) from the result in footnote (5).

The following table summarizes the potential profit that the Purchasers may achieve from the convertible notes and warrants. For purposes of the table, we have assumed the full amount of the principal of the convertible notes is converted at the related conversion price ($0.235) and full exercise of the warrants. We also have given the potential profit calculations assuming different price levels of our common stock. The second, third and fourth market prices were arbitrarily selected based on the recent trading history of the common stock.

Market Price	Total Possible Profit on Convertible Note Shares	Total Possible Profit on Warrant Shares	Total
$0.16	$ (806,000)	($ 864,000)	($ 1,670,000)
$0.20	$ (376,000)	($ 606,000)	($ 982,000)
$0.30	$ 698,000	$ 39,000	$ 737,000
$0.40	$ 1,773,000	$ 683,000	$ 2,456,000

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.

Under the Securities Purchase Agreement, as amended, we agreed to file this registration statement with the SEC to register the resale of 17,978,724 shares of common stock issuable pursuant to the 2008 Financing, referred to herein as the subsequent registrable shares, within 30 days of the related Closing. Also, we have agreed to respond to all SEC comment letters as promptly as reasonably possible and to use our best efforts to have this registration statement declared effective within 90 days of the related Closing. However, as of the date of this registration statement, we are unable to register 9,044,649 of the subsequent registrable shares in accordance with the rules and regulations of the SEC. Therefore, we are only filing this registration statement with the SEC to register the resale of 8,934,075 subsequent registrable shares issuable pursuant to the 2008 Financing. The value of the total number of subsequent registrable shares that we are currently registering pursuant to the Securities Purchase Agreement, as amended, based on the price per share of our common stock on January 28, 2009 is $2,948,245, based on average of the high and low prices of our common stock on January 28, 2009, or $0.33 per share. There is no guarantee that the SEC will declare this registration statement effective. In connection with our reduction of subsequent registrable shares being registered on this 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 this 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 investor, 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).

The purchasers of the convertible notes represented that each such purchaser is an accredited investor 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.

The gross proceeds from the convertible notes issued in the Subsequent Closing will be $2,525,000. The following table summarizes the potential payments we may be required to pay to the Purchasers. For purposes of this table, we have assumed that the entire $2,525,000 aggregate principal amount of the convertible notes were issued and sold on October 17, 2008 and that the Purchasers exercise all of the warrants on a cashless basis. The table reflects all the payments of fees, interest and premiums due during the term of the convertible notes and warrants.

Total Gross Proceeds Payable to Company(1)	Total Maximum Payments by Company(2)	Net Proceeds to Company(3)
$2,525,000	$283,280	$2,241,720

(1) Total gross proceeds payable to us. If Purchasers exercise the warrants on a cash basis, then the additional gross proceeds payable to us will be $1,895,362.

(2) Total maximum payments that have been paid and may be payable in connection with the facility, including legal expenses of approximately $30,000, interest of approximately $126,250 and maximum liquidated damages of $127,030.

(3) Total net proceeds to us calculated by subtracting the result in footnote (2) from the result in footnote (1). If Purchasers exercise the warrants on a cash basis, then the total net proceeds payable to us will be $4,137,082. The expenses set forth in column #2 above will not change in the event of the cash exercise of the warrants.

The following table sets forth the number of shares of our common stock issued and outstanding and issued and outstanding held by non-affiliates of the company, and the number of shares which have been registered for resale by Purchasers as a percentage of both numbers.

Total Number of Shares Outstanding(1)	Total Number of Shares held by Non-Affiliates of the Company	Total Number of Shares Registered for Resale by Selling Security Holder	Total Number of Shares Registered for Resale by Selling Security Holder in the Prior Registration Statement	Resale Shares as a Percent of Outstanding	Resale Shares as a Percent of Non-Affiliates
61,061,374	54,793,804	8,934,075	8,000,000	27.73%	30.91%

(1) As of March 20, 2009.

Prior Securities Transactions between the Company and the Purchasers

The following table indicates all prior securities transactions between the Company and Purchasers:

Date of the Transaction	Total Number of Shares Outstanding Prior to the Transaction	Total Number of Shares held by Non-Affiliates (1) of the Company Prior to the Transaction	Total Number of Shares Issued to the Selling Security Holder in the Transaction	Shares as a Percentage of Non-Affiliates (1)	Market Price Per Share Immediately Prior to the Transaction	Current Market Price Per Share (2)
May 26, 2005	33,834,294	27,751,050	6,231,590(3)	22.46%	$1.20	$0.29
April 19, 2006	40,766,827	30,845,938	896,562(4)	2.91%	$1.61	$0.29
December 27, 2006	49,491,749	41,836,197	1,346,680(5)	3.22%	$1.66	$0.29

(1) This calculation excludes any shares held by the Selling Security Holder in the denominator.

(2) Market price per share of our common stock on March 20, 2009.

(3) Consists of 4,615,993 shares of Common Stock and warrants to purchase 1,615,597 shares of Common Stock that are exercisable for a five-year period commencing upon the six month anniversary of the closing date.

(4) Consists of 689,663 shares of Common Stock and warrants to purchase 206,899 shares of Common Stock that are exercisable for a five-year period commencing upon the six month anniversary of the closing date.

(5) Consists of 961,914 shares of Common Stock and warrants to purchase 384,766 shares of Common Stock that are exercisable for a five-year period commencing upon the six month anniversary of the closing date.

Material Terms of the May 26, 2005 Transaction

On May 26, 2005, we closed a private placement with certain institutional and accredited investors for 6,733,024 shares of our Common Stock, at a purchase price of $1.05 per share, and Class D warrants to purchase 2,356,559 shares of Common Stock, with an exercise price of $1.30 per share. The shares of Common Stock issued in this private placement were issued at a discount to the market value of our Common Stock based on the last closing sale price of our Common Stock on the day immediately prior to the execution of the securities purchase agreement. We received gross proceeds of approximately $7,069,675 and net proceeds of approximately $6,300,000.

In connection with this transaction, we paid a cash commission equal to 7% of the gross proceeds from the offering to Paramount BioCapital, Inc., who acted as placement agent, and issued the placement agent a warrant to purchase 336,651 shares of Common Stock, with an exercise price of $1.30 per share. The placement agent was also entitled to an expense allowance of up to $50,000 to reimburse it for out of pocket expenses.

We also entered into a registration rights agreement that provides for the registration for resale of (i) shares of Common Stock sold in connection with the transaction, (ii) the shares of Common Stock issuable upon exercise of the Class D warrants and the placement agent warrants and (iii) any shares of Common Stock issued or issuable with respect to any of the foregoing following a stock split, stock dividend, recapitalization, exchange or similar event. We were required to file a registration statement for the resale of these shares within 45 days of the related closing date, and to use commercially reasonable efforts to have the registration statement declared effective with 90 days of the related closing date. Failure to file or to cause the registration statement to become effective with the required timeframe was subject to liquidated damages in cash equal to 1% of the aggregate purchase price of such shares for each 30-day period until such failure is cured.

ProQuest Investments purchased 4,615,993 shares of Common Stock and warrants to purchase 1,615,597 shares of Common Stock in this transaction.

Material Terms of the April 19, 2006 Transaction

On April 19, 2006, we closed a private placement with certain institutional and accredited investors for 8,092,796 shares of our Common Stock, at a purchase price of $1.45 per share, and warrants to purchase 2,427,839 shares of Common Stock, with an exercise price of $1.60 per share. The shares of Common Stock issued in this private placement were issued at a discount to the market value of our Common Stock based on the last closing sale price of our Common Stock on the day immediately prior to the execution of the securities purchase agreement. Our affiliates that invested in the private placement purchased shares of Common Stock at $1.58 per share, which was equal to the last closing sale price of our Common Stock on the day immediately prior to the execution of the securities purchase agreement. We received gross proceeds equal to $11,773,962.70 and net proceeds of approximately $10,400,000.

In connection with this transaction, we paid a cash commission equal to 7% of the gross proceeds from the offering to Paramount BioCapital, Inc. and Griffin Securities, Inc., who acted as placement agents, and issued the placement agents warrants to purchase 468,329 shares of Common Stock, with an exercise price of $1.60 per share.

We also entered into a registration rights agreement that provides for the registration for resale of shares of Common Stock sold in connection with the transaction and any shares of Common Stock issued or issuable following a stock split, stock dividend, recapitalization, exchange or similar event. We were required to file a registration statement for the resale of these shares within 30 days of the related closing date, and to use commercially reasonable efforts to have the registration statement declared effective with 90 days of the related closing date. Failure to file or to cause the registration statement to become effective with the required timeframe was subject to liquidated damages in cash equal to 1% of the aggregate purchase price of such shares for each 30-day period until such failure is cured.

ProQuest Investments purchased 689,663 shares of Common Stock and warrants to purchase 206,899 shares of Common Stock in this transaction.

Material Terms of the December 27, 2006 Transaction

On December 27, 2006, we closed a private placement with certain institutional and accredited investors for 9,823,983 shares of our Common Stock, at a purchase price of $1.45 per share, and warrants to purchase 3,929,593 shares of Common Stock, with an exercise price of $1.70 per share. The shares of Common Stock issued in this private placement were issued at a discount to the market value of our Common Stock based on the last closing sale price of our Common Stock on the day immediately prior to the execution of the securities purchase agreement. We received gross proceeds equal to approximately $14 million and net proceeds of approximately $13 million.

In connection with this transaction, we paid a cash commission equal to 7% of the gross proceeds from the offering to Oppenheimer & Co. Inc., who acted as placement agent, and issued the placement agent a warrant to purchase 491,199 shares of Common Stock, with an exercise price of $1.70 per share.

ProQuest Investments purchased 961,914 shares of Common Stock and warrants to purchase 384,766 shares of Common Stock in this transaction.

Prior Registration Statements of the Purchasers

The following table illustrates the number of shares of the Company s common stock registered for resale by the Purchaser in this registration statement and in prior registration statements.

Total Number of Shares Outstanding Prior to the 2008 Financing held by Non-Affiliates	Number of Shares Registered for Resale by the Selling Shareholder in Prior Registration Statements	Number of Shares Registered for Resale by the Selling Shareholder that Continue to be Held by the Selling Shareholder	Number of Shares that have been Sold in Registered Resale Transactions by the Selling Shareholder	Number of Shares Registered for Resale in this Registration Statement
50,802,227	16,474,832	16,474,832		8,934,075

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About NovaDel

We have a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2008 of $74,829,000, as compared to $65,243,000 as of December 31, 2007. Additionally, we have had negative cash flow from operating activities of $5,533,000 for the year ended December 31, 2008, $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five-months ended December 31, 2006 and $8,855,000 for the fiscal year ended July 31, 2006. As of December 31, 2008, we had working capital of $47,000 as compared to $3,811,000 as of December 31, 2007, representing a net decrease in working capital of approximately $3,764,000.

We are seeking to raise additional capital in early 2009 to fund our operations and 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 the Purchasers, to which we have issued $4.0 million of secured convertible notes in fiscal 2008, consisting of $1.5 million of notes issued in the initial closing on May 30, 2008, referred to herein as the Initial Closing Notes, and $2.5 million of notes issued in the subsequent closing on October 17, 2008, referred to herein as the Subsequent Closing Notes, demands payment under such notes. Given our current level of spending, if the Purchasers demand 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 the Purchasers only demand payment under the Initial Closing Notes, fully convert the 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 May 2009. If the Purchasers only demand payment under the Subsequent Closing Notes, fully convert the Initial 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 April 2009. Lastly, if the Purchasers choose not to demand payment on the Initial Closing Notes and the Subsequent Closing Notes, and instead fully convert them 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 the early third quarter 2009.

In addition, we have agreed to pay the Purchasers, 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 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 the Purchasers, 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).

Since the fourth quarter 2007 and continuing throughout 2008, 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. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to 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 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. 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. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

On May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange), referred to herein as the NYSE Amex, indicating that we are not in compliance with certain of the NYSE Amex continued listing standards. Specifically, the NYSE Amex has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex 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 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, 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 listing, we were required to submit a plan by June 13, 2008, advising the NYSE Amex 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 that we intended to submit such a plan, and did so on June 12, 2008.

On July 30, 2008, NYSE Amex notified us that the NYSE Amex 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, we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Amex is continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of December 31, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Amex 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 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 we submitted to the NYSE Amex 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 that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex Company Guide. Our deadline to regain compliance with Section 1003(a)(i), (ii) and (iii) remains November 16, 2009.

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

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

At our inception in 1982, then known as Pharmaconsult, we consulted to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992, we have used our consulting revenues to fund our own product development activities, supplemented by equity financing. Our focus on developing our own product candidates evolved naturally out of our consulting experience for other pharmaceutical companies. Substantially all of our revenues previously were derived from our consulting activities. Consulting activities are no longer a material part of our business. In 1991, we changed our name to Flemington Pharmaceutical Corporation. Effective October 1, 2002, we again changed our name to NovaDel Pharma Inc.

On June 28, 2006, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. Accordingly, the new fiscal year began on January 1 and ended on December 31. We filed a Transition Report on Form 10-K for the five months ended December 31, 2006. As such, the end of the quarters in the new fiscal year does not coincide with the end of the quarters in the previous fiscal years. Due to significant costs, we are not recasting the quarterly data from the previous fiscal years as such costs would exceed any potential benefits. Instead, we are presenting financial statements and other financial information, including Management s Discussion and Analysis of Financial Condition and Results of Operations, for the years ended December 31, 2008 and 2007, the five months ended December 31, 2006, and the fiscal year ended July 31, 2006. In Management s Discussion and Analysis of Financial Condition and Results of Operations, the year ended December 31, 2008 is compared to the year ended December 31, 2007 and the unaudited year ended December 31, 2006, and the five months ended December 31, 2006 are compared to the unaudited five months ended December 31, 2005. There are no seasonal or other significant factors which affect comparability.

Highlights for the year ended December 31, 2008, and additionally through the date of filing of this prospectus, include the following product development and business achievements:

Product Pipeline

- Announced that our New Drug Application for Zolpimist to treat insomnia was accepted for filing by the U.S. Food and Drug Administration.
- Announced the results of a clinical study comparing our tizanidine oral spray with tizanidine tablets, where our oral spray met primary pharmacokinetic and pharmacodynamic and safety objectives.
- Announced the results of a pilot efficacy study comparing our NVD-201 with Imitrex® tablets, where our oral spray was safe and effective in relieving migraine headaches at a lower dosage than that for the Imitrex® tablets.
- Announced that the U.S. Food and Drug Administration had requested an extension of up to three months on our New Drug Application for Zolpimist in order to complete their review.
- Updated our website and corporate presentation for our new product pipeline, as discussed further below.
- Announced that Par Pharmaceuticals had recently completed bioequivalence studies on Zensana with mixed results, and that Par would be working with us to carefully review and understand the results of the studies before determining the next steps for Zensana .
- Announced that our New Drug Application for Zolpimist to treat insomnia was approved by the U.S. Food and Drug Administration.

Intellectual Property

- Received notification of the issuance of additional patents in Canada and Europe which further strengthens our intellectual property position in the oral delivery of pharmaceuticals. The issued patents cover the use of multiple classes of drugs in oral sprays, including those for the treatment of pain, and for central nervous system disorders under our oral spray delivery system in Canada, and analgesics, alkaloids, and nicotine in Europe.

Other

- Announced that we had entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P. for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock.
- Announced that we had entered into a European partnership with BioAlliance Pharma SA for the development and commercialization of our ondansetron oral spray, or OS, for Europe.
- Announced that we had entered into amendment no. 1 to the securities purchase agreement in connection with the 2008 Financing to clarify certain terms of the securities purchase agreement.
- Announced that we had closed the initial portion of the 2008 Financing, referred to herein as the Initial Closing, for an aggregate gross proceeds of $1,475,000, in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

Announced that we received a notification from NYSE Amex that we were not in compliance with certain of the NYSE Amex continued listing standards. On June 12, 2008, we submitted a plan of compliance to the NYSE Amex for review. On July 30, 2008, NYSE Amex 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 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 Company Guide. The NYSE Amex is continuing our listing pursuant to an extension, subject to certain conditions.

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

Announced that Michael E. Spicer intends to resign 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 our 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.

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 hypnotic 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, in November 2008, Par 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 to determine the work necessary to complete Zensana s development and proceed with an NDA submission.

In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA on June 30, 2006 and such NDA was accepted for review by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA.

We will receive a milestone payment from Hana Biosciences upon final approval of the NDA by 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). Relative bioavailability after administration of 20mg NVD-201 appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including multiple sclerosis, spinal cord injury, stroke and cerebral palsy, which leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in view of the higher priority associated with our current product pipeline as described above, we do not anticipate further development of tizanidine oral spray due to commercial and operational priorities.

Ropinirole oral spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson s disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson s are 65 years of age or older and it is estimated that 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We were previously targeting an NDA submission for our ropinirole product candidate in calendar 2008. However, in view of the higher priority associated with our current product pipeline as described above, we do not anticipate further development of ropinirole oral spray due to commercial and operational priorities.

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Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product candidate. On July 10, 2007, Manhattan Pharmaceuticals announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

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

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

THE OFFERING

Number of shares of our common stock offered by the selling security holders	8,934,075[(1)] shares
Number of shares of our common stock outstanding after the offering	77,995,449[(2)] shares
Use of proceeds	We will not receive any proceeds from the sale of common stock by the selling security holders. We may receive the proceeds from the exercise of warrants held by the selling security holders, if any are exercised. Any such proceeds will be used primarily for increased or additional research and development and general working capital. However, the selling security holders have the right to exercise the warrants pursuant to a cashless exercise provision, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders.
NYSE Amex symbol	NVD

(1) Includes the conversion of the convertible notes from the Subsequent Closing into 8,934,075 shares of common stock.

(2) Based upon 61,061,374 shares of common stock issued and outstanding as of March 20, 2009, after giving effect to the conversion of the convertible notes into 8,934,075 shares of common stock, and including 5,000,000 shares of common stock to be issued upon the conversion of the convertible notes issued in the Initial Closing and 3,000,000 shares of common stock upon the exercise of outstanding warrants issued in the Initial Closing.

RISK FACTORS

One should carefully consider the following risk factors and all other information contained in this prospectus before investing in our common stock. Investing in our common stock involves a high degree of risk. Any of the following risks could adversely affect our business, financial condition, results of operations, performance, achievements and industry and could result in a complete loss of one s investment. The risks and uncertainties described below are not the only ones we may face.

RISKS RELATED TO OUR BUSINESS

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

Our audited financial statements for the 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. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.

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

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

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

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

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

cease operations; or

declare bankruptcy.

We are seeking to raise additional capital in early 2009 to fund our operations and 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 issued $4.0 million of secured convertible notes in fiscal 2008, consisting of $1.5 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. 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 only demands payment under the Initial Closing Notes, fully convert the 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 May 2009. If ProQuest only demands payment under the Subsequent Closing Notes, fully convert the Initial 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 April 2009. Lastly, if ProQuest chooses not to demand payment on the Initial Closing Notes and the Subsequent Closing Notes, and instead fully convert them 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 the early third quarter 2009. Subsequent to December 2008, and as of the date of this prospectus, although ProQuest did not convert its notes into common stock, ProQuest has not yet demanded payment under the notes.

In addition, we have agreed to pay ProQuest, as 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).

We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007 and continuing throughout 2008, 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. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations. We 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. There can be no assurance that such capital will be available to us on favorable terms, or at all.

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

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. Given the recent downturn in the economy, we can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us. Since the fourth quarter 2007 and continuing throughout 2008, 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. The convertible notes issued in the Initial Closing

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mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000.

Given 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 only demands payment under the Initial Closing Notes, fully converts the 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 May 2009. If ProQuest only demands payment under the Subsequent Closing Notes, fully converts the Initial 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 April 2009. Lastly, if ProQuest chooses not to demand payment on the Initial Closing Notes and the Subsequent Closing Notes, and instead fully converts them 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 the early third quarter 2009. Subsequent to December 2008, and as of the date of this prospectus, although ProQuest did not convert its notes into common stock, ProQuest has not yet demanded payment under the notes.

In addition, we have agreed to pay ProQuest, as 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).

We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007 and continuing throughout 2008, 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.. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations. We 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. There can be no assurance that such capital will be available to us on favorable terms, or at all.

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

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. 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 both NitroMist and Zolpimist . We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future. Since the fourth quarter 2007 and continuing throughout 2008, 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. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as 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).

However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. Given the recent downturn in the economy, there can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

We had an accumulated deficit as of December 31, 2008 of approximately $74,829,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $9,586,000 for the year ended December 31, 2008, $16,963,000 for the year ended December 31, 2007, $3,805,000 for the five months ended December 31, 2006 and $10,084,000 for the fiscal year ended July 31, 2006. Additionally, we have reported negative cash flows from operations of approximately $5,533,000 for the year ended December 31, 2008, $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five months ended December 31, 2006 and $8,855,000 for the fiscal year ended July 31, 2006. We anticipate that, even with our limited research and development activities, we could incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Given the recent downturn in the economy, we may not be able to secure such additional financing on terms acceptable to

us, if at all. We have the authority to issue additional shares of our common stock, as well as

additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

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

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance.

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

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

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

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

As of March 20, 2009, ProQuest Investments, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 38.1% of our outstanding common stock (assuming exercise of certain warrants held by ProQuest Investments). As such, ProQuest Investments may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Interim President and Chief Executive Officer, has served as a venture partner with ProQuest Investments since December 2004, although he has no authority for investment decisions by ProQuest Investments.

Through December 31, 2008, Dr. Lindsay Rosenwald beneficially owned approximately 5.2% of our outstanding common stock and was deemed to be our affiliate through that time. As an affiliate, Dr. Rosenwald had the ability to designate an individual to serve on our Board of Directors, or the Board, and had exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell was a designee of Dr. Rosenwald s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald, and in addition Dr. Rosenwald has ceased to be an affiliate of ours, as a result of his disposition of certain shares of our common stock and the expiration of certain warrants to purchase our common stock. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the NYSE Amex LLC, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences, each of which company has entered into a license agreement with us. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. As of March 20, 2009, Dr. Rosenwald beneficially owned approximately 2.2% of our outstanding common stock and, therefore, would no longer be considered an affiliate.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. Since the fourth quarter 2007 and continuing throughout 2008, 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. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as 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).

However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. Given the recent downturn in the economy, there can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities. See Risk Factors - We Will Require Significant Capital For Product Development And Commercialization and Our Strategy Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates And We May Require Additional Collaboration Agreements. If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products.

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

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

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of the calendar year 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. 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 both NitroMist and Zolpimist . Our partner for Zensana , Par Pharmaceuticals, recently announced that it had completed

bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana . Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us. Since the fourth quarter 2007 and continuing throughout 2008, 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. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as 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).

However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. 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 both NitroMist and Zolpimist . Our partner for Zensana , Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana . Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations. Furthermore, since the fourth quarter 2007 and continuing throughout 2008, 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. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee

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of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as 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).

However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

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

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

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

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

WE ARE DEPENDENT ON OUR SUPPLIERS.

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX USA, Ltd., whereby Inyx shall manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. On July 3, 2007, INyX, our manufacturer for our NitroMist product candidate, announced it filed for protection under the Chapter 11 bankruptcy laws. In June 2008, the trustees for INyX informed us that the facility in Manati, Puerto Rico would cease operations at the end of July 2008. As a result, we selected an alternative manufacturer for NitroMist , DPT Laboratories Inc, and are in the process of transferring manufacturing operations to DPT.

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

With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of Dynamit Nobel, DPT Laboratories, or Rechon Life Sciences to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS AND OPERATING RESULTS. IN ADDITION, CURRENT AND POTENTIAL STOCKHOLDERS COULD LOSE CONFIDENCE IN OUR FINANCIAL REPORTING, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR STOCK PRICE.

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

We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

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

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

WE FACE INTENSE COMPETITION.

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

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

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

LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.

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

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EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal U.S. regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product s safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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

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

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

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

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

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

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

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

Our strategy for the completion of the required development and clinical testing of certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products.

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

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

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

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

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

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

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners expertise and dedication of sufficient resources to develop and commercialize proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana in June 2006. The safety and efficacy of the drug will be based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the trade name Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us and/or Hana Biosciences for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences has announced that it has not received any objections related to these patent certifications. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA.

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

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

We, and the parties licensing technologies to us, have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Currently, we have eight patents which have been issued in the U.S. and 64 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the USPTO or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our product candidates and processes in the U.S. and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also Risk Factors - If We Cannot Meet Requirements Under our License Agreements, We Could Lose the Rights to our Products.

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

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

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

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

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

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

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

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

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

WE ARE DEPENDENT ON EXISTING MANAGEMENT AND BOARD MEMBERS.

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

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

RISKS RELATED TO OUR COMMON STOCK

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

Our common stock is currently listed for trading on the NYSE Amex LLC, or NYSE Amex, and the continued listing of our common stock on the NYSE Amex is subject to our compliance with a number of listing standards. These listing standards include the requirement for maintaining stockholders equity of at least $6,000,000. As of December 31, 2008, our net worth position was a deficit of $2,741,000 and as of December 31, 2007, our net worth position was $4,174,000, which are each below the minimum net worth continued listing requirement. On May 14, 2008, we received a notice from NYSE Amex providing notification that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholder s equity of less than $6,000,000 and losses from continuing operations and net losses in the five most recent fiscal years and Section 1003(a)(iv) of the NYSE Amex 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, as to whether we will be able to continue operations and/or meet our obligations as they mature. We submitted a plan to the NYSE Amex on June 12, 2008 advising of the actions we have taken, and will take, that would bring us into compliance with Section 1003(a)(iii) by November 16, 2009 and Section 1003(a)(iv) by November 14, 2008. On July 30, 2008, NYSE Amex notified us that the NYSE Amex 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, we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods, which completion dates are November 14, 2008 with respect to Section 1003(a)(iv) and November 16, 2009 with respect to Section 1003(a)(iii). Therefore, the NYSE Amex is continuing our listing pursuant to an extension, subject to certain conditions.

In addition, as of December 31, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Amex 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 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 we submitted to the NYSE Amex 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 that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex Company Guide. Our deadline to regain compliance with Section 1003(a)(i), (ii) and (iii) remains November 16, 2009.

There can be no assurance that we will be able to make progress consistent with our plan to regain compliance with NYSE Amex 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 Company Guide.

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

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

WE ARE INFLUENCED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of March 20, 2009, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 40.3% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest Investments has the ability to exert significant influence over matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

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

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

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

Our common stock has been listed for quotation on the NYSE Amex since May 11, 2004 under the symbol NVD. Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the twelve-month period ended December 31, 2008, the closing price of our common stock has ranged from $0.06 to $0.51. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve-month period ended December 31, 2008, the average daily trading volume in our common stock was approximately 296,687 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

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

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

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

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

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

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

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- boiler room practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

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

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

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of March 20, 2009, there were 61,061,374 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants, or the conversion of our convertible notes. As of March 20, 2009, we had outstanding stock options and warrants to purchase approximately 27.7 million shares of common stock, the exercise prices of which range between $0.21 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

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In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 27.7 million shares of common stock as of March 20, 2009 noted above.

On October 17, 2008, an additional $2,525,000 of secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock. We issued 6,446,809 warrants, which have an exercise price of $0.294 per share, and are included in the total outstanding stock options and warrants to purchase approximately 27.7 million shares of common stock as of March 20, 2009 noted above.

The following table provides an overview of our stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at March 20, 2009	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000		Plan Closed
1997 Stock Option Plan	500,000	50,000		Plan Closed
1998 Stock Option Plan	3,400,000	1,906,000	1,199,000	
2006 Equity Incentive Plan	6,000,000	4,899,000	21,000	
Non-Plan	n/a	730,000		
Total	**10,400,000**	**7,625,000**	**1,220,000**	

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

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

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

SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a six-month holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a one-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

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

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

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

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

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

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

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

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

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

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

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

In May 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our common stock, and certain warrants to purchase 2,693,210 shares of our common stock. The sales of the shares of common stock and warrants resulted in gross proceeds to us of approximately $7.1 million, prior to offering expenses.

The offering of, and/or resale of our common stock and the exercise of the warrants described immediately above in this risk factor are subject to currently effective registration statements filed by us on Forms S-3. There can be no assurance as to the prices at which our common stock will trade in the future, although they may continue to fluctuate significantly. Prices for our common stock will be determined in the marketplace and may be influenced by many factors, including the following:

- The depth and liquidity of the markets for our common stock;
- Investor perception of us and the industry in which we participate; and
- General economic and market conditions.

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

As of March 20, 2009, we have 61,061,374 shares of common stock issued and outstanding and approximately 27.7 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 34.6 million shares of common stock noted above. On October 17, 2008, $2,525,000 of additional secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock, and an additional 6,446,809 warrants were issued with an exercise price of $0.294 per share, which are not included in the 27.7 million shares of common stock for options and warrants noted above. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

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

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

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

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

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

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

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

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

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

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

We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.

We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel.

If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy. If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

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

We have entered into agreements with the holders of our common stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of common stock. Such registration statements were declared effective on July 16, 2008, January 26, 2007, May 30, 2006 and July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

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 are filing the registration statement with the SEC to register the resale of 8,934,075 subsequent registrable shares issuable pursuant to the 2008 private placement. There is no guarantee that the SEC will declare the registration statement effective. 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. 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).

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains some forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995 and information relating to us that are based on the beliefs of our management, as well as assumptions made by and the information currently available to our management. When used in this prospectus, the words estimate, project, believe, anticipate,

intend, expect and similar expressions are intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in these forward-looking statements, including those risks discussed in this prospectus. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. Except for special circumstances in which a duty to update arises when prior disclosure becomes materially misleading in light of subsequent circumstances, we do not intend to update any of these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares owned by the selling security holders. However, we will receive proceeds from the exercise of outstanding warrants, if such warrants are exercised. However, the warrants contain provisions for cashless exercise, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders. The warrants entitle the selling security holders to purchase shares of our common stock at an exercise price of $0.294 per share. Any such proceeds will be used primarily for increased or additional research and development and general working capital.

The selling security holders will pay any underwriting discounts and commissions and expenses incurred by the selling security holders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the issuance and registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, American Stock Exchange listing fees and fees and expenses of our counsel and our accountants.

SELLING SECURITY HOLDERS

The following is a summary of the transactions by which the selling security holders acquired the securities being registered by this prospectus.

On May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, between the Company and the Purchasers, to sell up to $4,000,000 of convertible notes and accompanying warrants. In connection with this agreement, $1,475,000 of convertible notes and accompanying warrants were funded on May 30, 2008 at the Initial Closing. The convertible notes issued in the Initial Closing convert into our common stock at a fixed price of $0.295 per share, or 5,000,000 shares of common stock, subject to certain adjustments. In addition, we issued warrants to purchase 3,000,000 shares of our common stock, which have an exercise price of $0.369 per share. The maturity date of the convertible notes issued in the Initial Closing is November 30, 2008.

On October 17, 2008, we closed on an additional $2,525,000 of secured convertible notes and accompanying warrants with the Purchasers in the Subsequent Closing. The convertible notes issued in the Subsequent Closing are convertible into 10,744,681 shares of our common stock, with a conversion price of $0.235 per share. We also issued 6,446,809 warrants, which have an exercise price of $0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing is April 17, 2009.

The following table sets forth the aggregate number of shares of common stock beneficially owned by the selling security holders as of March 20, 2009, after giving effect to the private placement, and the percentage of all shares of common stock held by such selling security holders prior to and without giving effect to the offering based on 61,061,374 shares of common stock outstanding as of March 20, 2009. Except as described in this prospectus, the selling security holders have not held any position or office or had any other material relationship with us or any of our predecessors or affiliates within the past three years.[1] We considered the following factors and made the following assumptions regarding the table:

- beneficial ownership is determined under Section 13(d) of the Securities Exchange Act of 1934 (Exchange Act) and generally includes voting or investment power with respect to securities and including any securities that grant the selling security holder the right to acquire Common Stock within 60 days of March 20, 2009; and

- the selling security holders may sell all of the securities offered by this prospectus under certain circumstances.

Notwithstanding these assumptions, the selling security holders may sell less than all of the shares listed on the table. In addition, the shares listed below may be sold pursuant to this prospectus or in privately negotiated transactions. Accordingly, we cannot estimate the number of shares of Common Stock that the selling security holders will sell under this prospectus.

[1] Mr. Ratoff is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments, a health care venture capital firm.

Except as indicated in the footnotes to this table, the persons named in the table have sole voting and investment control with respect to all shares of our Common Stock shown as beneficially owned by them.

Name of Selling Security Holder [1]	Shares of Common Stock Beneficially Owned Prior to the Subsequent Closing [2]		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After the Subsequent Closing and Prior to this Offering [2]		Shares of Common Stock to be Beneficially Owned After this Offering [2][3]	
	Number	Percentage	Number	Number	Percentage	Number	Percentage
ProQuest Investments	16,474,832(4)	23.1%	8,934,075	25,408,907	31.7%	16,474,832	20.5%

(1) Based on the information we received from each known holder of the securities, except as disclosed below, no selling security holder is an affiliate of any registered broker-dealer.

(2) Shares of common stock issuable under stock options and warrants that are exercisable within 60 days after March 20, 2009 are deemed outstanding for computing the percentage ownership of the selling security holder holding the options or warrants, prior to and after giving effect to the offering, but are not deemed outstanding for computing the percentage ownership of any other selling security holder.

(3) The selling security holders may offer and sell all or a part of the common stock pursuant to this prospectus, but no estimates can be made as to the amount of shares of common stock that will be held by the selling security holders after the completion of this offering. None of the selling security holders are broker-dealers or in any way affiliated with any broker-dealer.

(4) Includes (i) 30,397 shares of common stock, 24,251 shares issuable upon the conversion of convertible notes in the Initial Closing, and warrants to purchase 25,255 shares of common stock held in the name of ProQuest Investments II Advisors Fund, L.P., (ii) 1,262,747 shares of common stock, 1,007,365 shares issuable upon the conversion of convertible notes in the Initial Closing, and warrants to purchase 1,049,123 shares of common stock held in the name of ProQuest Investments II, L.P., and (iii) 4,974,426 shares of common stock, 3,968,384 shares issuable upon the conversion of convertible notes in the Initial Closing, and warrants to purchase 4,132,884 shares of common stock held in the name of ProQuest Investments III, L.P. ProQuest Associates III LLC (Associates III) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC (Associates II) is the General Partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person s respective pecuniary interest in such securities.

PLAN OF DISTRIBUTION

We are registering the shares offered by this prospectus on behalf of the selling security holders. The selling security holders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling security holder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions.

These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling security holders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling security holders under this prospectus.

The selling security holders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling security holders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling security holders to include the pledgee, transferee or other successors in interest as selling security holders under this prospectus.

In connection with the sale of our common stock or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling security holders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling security holders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling security holders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling security holders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

Selling security holders who are registered broker-dealers are deemed to be underwriters within the meaning of the Securities Act. In addition, selling security holders who are affiliates of registered broker-dealers may be deemed to be underwriters within the meaning of the Securities Act if such selling stockholder (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act, and such selling security holders may be subject to certain additional regulations and statutory liabilities under the Securities Act and Exchange Act. To our knowledge and based upon information we received from the selling security holders, (i) the selling security holders are not registered broker-dealer or affiliated with a registered broker-dealer and have acquired the shares of common stock in the ordinary course of business, (ii) such selling security holders do not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock, and (iii) the selling security holders have not received any securities as underwriting compensation. We are also not aware of any underwriting plan or agreement, underwriters or dealers compensation, or passive market making or stabilizing transactions involving the purchase or distribution of these securities.

To the extent required, the shares of our common stock to be sold, the names of the selling security holders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling security holders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling security holders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling security holders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling security holders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling security holders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus. The selling security holders have agreed to indemnify us in certain circumstances against certain liabilities, including liabilities under the Securities Act.

We have agreed with the selling security holders to keep the registration statement that includes this prospectus effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold pursuant to Rule 144 of the Securities Act. We have agreed to pay all expenses in connection with this offering, but not including underwriting discounts, concessions, commissions or fees of the selling security holders or any fees and expenses of counsel or other advisors to the selling security holders.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Morgan, Lewis & Bockius, LLP, Princeton, New Jersey.

EXPERTS

The financial statements as of December 31, 2008 and 2007, and for the years ended December 31, 2008 and December 31, 2007, the five months ended December 31, 2006, and the fiscal year ended July 31, 2006 incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by J.H. Cohn LLP, independent registered public accounting firm, as indicated in their report with respect thereto, and are incorporated by reference herein in reliance upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Commission. You may read and copy any document we file at the Commission s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of the filings we make with the Commission are also available to the public from the Securities and Exchange Commission s Website at http://www.sec.gov. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to dzodda@novadel.com or contact Deni Zodda, our Interim Chief Financial Officer at our address as set forth above. In addition, our common stock is listed for trading on the NYSE Amex LLC under the symbol NVD. We maintain a Website at http://www.novadel.com (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this prospectus.

We have filed with the Commission a Registration Statement (which contains this prospectus) on Form S-3 under the Securities Act. The registration statement relates to the common stock offered by the selling security holders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the Commission, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the documents filed with the Commission listed below:

1. Our Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 30, 2009;

2. Our Current Reports on Form 8-K filed with the Commission on January 28, 2009, January 30, 2009 and March 25, 2009;

3. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the Commission on November 19, 1997, and May 10, 2004; and

4. All documents we have filed with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

You may request a copy of these filings, at no cost, by sending an e-mail to dzodda@novadel.com and requesting any one or more of such filings or by contacting Deni Zodda, our Interim Chief Financial Officer at the following address or telephone number: NovaDel Pharma Inc., 25 Minneakoning Road, Flemington, New Jersey 08822, Attention: Chief Financial Officer; (908) 782-3431. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

This prospectus is part of a registration statement we filed with the Commission. You should rely only on the information contained in this prospectus. We have authorized no one to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

WE HAVE NOT AUTHORIZED ANY DEALER, SALES PERSON OR OTHER PERSON TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS OR ANY PROSPECTUS SUPPLEMENT. THIS PROSPECTUS IS NOT AN OFFER OF THESE SECURITIES IN ANY STATE WHERE AN OFFER IS NOT PERMITTED. THE INFORMATION IN THIS PROSPECTUS IS CURRENT AS OF ITS DATE, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR OF ANY SALE OF THE SHARES. YOU SHOULD NOT ASSUME THAT THIS PROSPECTUS IS ACCURATE AS OF ANY OTHER DATE.

8,934,075 Shares of Common Stock

PROSPECTUS

_____, 2009

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the fees and expenses payable by us in connection with the registration of the common stock offered hereby. We shall bear all expenses in connection with the issuance and distribution of the securities being offered hereby, provided that normal commission expenses and brokerage fees are payable individually by the selling security holders. All amounts are estimated except the Commission registration fee.

Commission registration fee	$ 116.00
Additional Listing Fee	$ 15,000.00
Accounting fees and expenses	$ 7,500.00
Attorneys fees and expenses	$ 30,000.00
Miscellaneous	$ 5,000.00
Total	57,616.00

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law (the DGCL) empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of the performance of their duties as directors and officers. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation s by-laws, any agreement, vote of stockholders or otherwise.

Article Nine of our Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by Section 102 of the DGCL. Article Ten provides for indemnification of all persons whom we shall have the power to indemnify pursuant to Section 145 of the DGCL.

The effect of the foregoing is to require us, to the extent permitted by law, to indemnify our officers and directors for any claims arising against such persons in their official capacities if such persons acted in good faith and in a manner that they reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

We currently have liability insurance coverage for our officers and directors.

Item 16. Exhibits.

Exhibit No.	Description
4.1	Form of Convertible Note issued to certain accredited investors (Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on June 3, 2008).
4.2	Form of Warrant issued to certain accredited investors (Incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed June 3, 2008).
5.1*	Opinion of Morgan, Lewis & Bockius LLP.
10.1	Securities Purchase Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. (Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed June 3, 2008).
10.2	Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. (Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed June 3, 2008).
10.3	Security and Pledge Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. as secured parties and ProQuest Investments III, L.P. as collateral agent (Incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K, filed June 3, 2008).
23.1*	Consent of J.H. Cohn LLP.
23.2*	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1).
24.1	Power of Attorney (Incorporated by reference to Exhibit 24.1 of our Registration Statement on Form S-3, filed on November 13, 2008).

* Filed herewith.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement:

(i) to include any prospectus required by section 10(a)(3) of Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission, or the Commission, pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a twenty percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that

(A) paragraphs (a)(1)(i) and (a)(1)(ii) of this section do not apply if the registration statement is on Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement; and; and

(B) paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of this registration statement as of the date the filed prospectus was deemed part of and included in this registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of this registration statement or in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in this registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of this registration statement relating to the securities in this registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in this

registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is part of this registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in this registration statement or prospectus that was part of this registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in this registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in this registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is part of this registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in this registration statement or prospectus that was part of this registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(d) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its

counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Flemington, State of New Jersey, on April 6, 2009.

NOVADEL PHARMA INC.

By: /s/ STEVEN B. RATOFF

Steven B. Ratoff
Chairman, Interim President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 2 to the registration statement has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURES	TITLE	DATE
/S/ STEVEN B. RATOFF Steven B. Ratoff	Chairman, Interim President and Chief Executive Officer (Principal Executive Officer)	April 6, 2009
/S/ DENI M. ZODDA Deni M. Zodda	Interim Chief Financial Officer (Principal Financial Officer)	April 6, 2009
/S/ JOSEPH WARUSZ Joseph Warusz	Principal Accounting Officer	April 6, 2009
* Mark J. Baric	Director	April 6, 2009
* Thomas E. Bonney	Director	April 6, 2009
* William F. Hamilton, Ph.D.	Director	April 6, 2009
* J. Jay Lobell	Director	April 6, 2009
* Charles Nemeroff	Director	April 6, 2009
By: /S/ STEVEN B. RATOFF Steven B. Ratoff	Attorney-in-fact	April 6, 2009

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