NOVADEL PHARMA INC
Form S-3/A
February 02, 2009

As filed with the Securities and Exchange Commission on February 2, 2009

Registration Statement No. 333-155345

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT NO. 1 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 x (Do not check if smaller reporting company)	Smaller reporting company o

CALCULATION OF REGISTRATION FEE

Title of Shares To Be Registered	Amount To Be Registered	Proposed Maximum Aggregate Price Per Share	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee
Common Stock, $0.001 par value	8,934,075(1)	$0.33(2)	$2,948,245	$116.00(3)

(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) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c). Such price is based upon the average of the high and low prices of the registrant's common stock as reported on the NYSE Alternext US LLC on January 28, 2009.

(3) 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 February 2, 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" refer 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 Alternext US LLC (formerly known as the American Stock Exchange), or Alternext, under the symbol "NVD." On January 28, 2009, the closing sales price for our common stock on the Alternext was $0.33 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE "RISK FACTORS" SECTION BEGINNING ON PAGE 21 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

TABLE OF CONTENTS

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 Alternext US LLC (formerly known as the American Stock Exchange), referred to herein as Alternext, and satisfaction of customary closing conditions. The 5,000,000 shares, along with the prior securities owned by the Purchasers, represented 19.8% of 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 Alternext 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 to our existing capital leases (approximately $491,000 in net book value of fixed assets as of September 30, 2008, on which $183,000 of capital lease obligations exist at September 30, 2008); (ii) the assets marked as Assets held for sale on our balance sheet as of September 30, 2008, which represented assets associated with our NitroMist product which is currently being targeted for sale, the amount for which was $178,000 as of September 30, 2008; and (iii) the assets marked as Other Assets on our balance sheet as of September 30, 2008, which represented assets held as security for our letters of credit and leased assets, the amount for which was $296,000 as of September 30, 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 partial liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the Purchasers for any convertible notes then held by the Purchasers, but these payments may not exceed 10% of the aggregate purchase price paid by the Purchasers.

The 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)**	
Existing Stockholders (other than ProQuest Investments) (1)(2):	**Number**	**Percentage**	**Number**	**Percentage**
	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	23.3%	34,453,556	38.9%

(1) Ownership is based upon the number of outstanding shares of common stock as of January 28, 2009, includes all options, warrants and other convertible securities held by ProQuest Investments exercisable within 60 days of January 28, 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 January 28, 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 September 30, 2008 was approximately a deficit of $1.7 million, or approximately ($0.025) per share, based on 68,692,260 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 as of September 30, 2008, and including shares underlying all convertible notes and warrants issued in 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 September 30, 2008 and the consummation of the Subsequent Closing, our stockholders equity would have improved to a deficit of approximately $1.1 million, or approximately ($0.012) per share, based on 86,670,984 shares of our common stock outstanding, and including shares underlying all convertible notes and warrants in the Initial Closing and the Subsequent Closing, as well as potential interest shares issuable pursuant to the Initial Closing and the Subsequent Closing. The increase in stockholders equity per share to existing stockholders in the Subsequent Closing is due to the inclusion of approximately $600,000 in stockholders equity related to the Subsequent Closing. The following table illustrates this per share dilution:

Stockholders equity per share as of September 30, 2008 and assuming the Subsequent Closing has not occurred	($0
Stockholders equity per share as of September 30, 2008 and assuming the Subsequent Closing has occurred	$0
Dilution per share to Purchasers.	$0

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 January 28, 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)**	
Existing Stockholders (other than ProQuest Investments) (1):	**Number**	**Percentage**	**Number**	**Percentage**
	82,552,521	83.4%	82,552,521	70.6%

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(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 January 28, 2009.

(2) Ownership is based upon the number of outstanding shares of common stock as of January 28, 2009 and includes all options, warrants and other convertible securities held by the Existing Stockholders exercisable within 60 days of January 28, 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 January 28, 2009, (b) the total number of options, warrants and other convertible securities exercisable within 60 days of January 28, 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 8,934,075 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. The value of the total number of shares of common stock 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, using a market price of $0.33 per share (based on average of the high and low prices of our common stock on January 28, 2009). There is no guarantee that the SEC will declare this registration statement effective. Upon certain events, we have agreed to pay as partial liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the investor for any convertible notes then held by the investor, but these payments may not exceed 10% of the aggregate purchase price paid by the investor.

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	$408,750	$2,116,250

(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 $252,500.

10

(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 $4,011,612. 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.

tal Number of Shares utstanding(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 Percent of Non- Affiliates
60,628,221	50,802,227	8,934,075	8,000,000	27.93%	33.33%

_____

(1) As of January 28, 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	$0.33
April 19, 2006	40,766,827	30,845,938	1,346,680 (4)	4.37%	$1.61	$0.33
December 27, 2006	49,491,749	41,563,946	896,562 (5)	2.16%	$1.66	$0.33

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(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 January 28, 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 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.

(5) 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.

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.

	Number of Shares	Number of Shares Registered for Resale by	Number of Shares that

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

About NovaDel

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

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

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

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

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

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

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

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

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

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

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

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

Highlights for the nine months ended September 30, 2008, and additionally through the date of filing of this Registration Statement, include the following:

Product Pipeline

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

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

Other

- Announced that we had entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P. for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock.
- Announced that we had entered into a European partnership with BioAlliance Pharma SA for the development and commercialization of our ondansetron oral spray (or OS) for Europe.
- Announced that we had entered into amendment no. 1 to the securities purchase agreement in connection with the 2008 Financing to clarify certain terms of the securities purchase agreement.
- Announced that we had closed the initial portion of the 2008 Financing (the Initial Closing) for an aggregate gross proceeds of $1,475,000, in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.
- Announced that we received a notification from NYSE Alternext that we were not in compliance with certain of the NYSE Alternext continued listing standards. On June 12, 2008, we submitted a plan of compliance to the NYSE Alternext for review. On July 30, 2008, NYSE Alternext notified us that it had completed its review of our proposed plan of compliance and has determined that we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods. The NYSE Alternext is continuing our listing pursuant to an extension, subject to certain conditions.
- Announced that we had closed on the subsequent portion of the 2008 Financing (the Subsequent Closing) for aggregate gross proceeds of $2,525,000 in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or FDA, or comparable regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a New Drug Application, or NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product□s safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and submission of an NDA, will require significantly less time and lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates may prove to be inaccurate; or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all, and research and development expenditures may significantly exceed management□s expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

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

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

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. The following table summarizes our product candidates:

	Active Ingredient or Class of Molecule	Indications	Stage of Development	Partner
Approved Product				
NitroMist™	nitroglycerin	Angina Pectoris	FDA Approved	-
Product Candidates				
Zolpimist™	zolpidem	Insomnia	FDA Approved	-
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. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pain is a common morbidity in cancer patients occurring in approximately 30% of newly diagnosed patients and 65-85% of advanced cancer patients. Opiates are commonly used to treat cancer pain, however approximately 65% of opiate treated cancer patients have acute pain episodes, called breakthrough cancer pain, which requires the use of a short-acting drug on top of the patients basic pain therapy regimen. There are two products approved in the United States for the treatment of breakthrough cancer pain with combined sales of approximately $500 million. The global market for breakthrough cancer products is predicted to grow to over $2 billion by 2016. Formulation development is ongoing with the objective of entering clinical trials in 2009, assuming that funding for such trials is available.

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

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

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

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

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

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

19

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	77,562,297[(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.
Alternext 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 60,628,221 shares of common stock issued and outstanding as of January 28, 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 unaudited condensed financial statements for the nine months ended September 30, 2008, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.

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

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

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

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

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

- declare bankruptcy.

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

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

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. Given the recent downturn in the economy, we can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000.

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

the sale of common stock or other securities. Given the recent downturn in the economy, there can be no assurance that such capital will be available to us on favorable terms, or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

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

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

We had an accumulated deficit as of September 30, 2008 of approximately $72,920,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $7,677,000 for the nine months ended September 30, 2008, $16,963,000 for the year ended December 31, 2007, $3,805,000 for the five months ended December 31, 2006, $10,084,000 for the fiscal year ended July 31, 2006 and $9,450,000 for the fiscal year ended July 31, 2005. Additionally, we have reported negative cash flows from operations of approximately $5,126,000 for the nine months ended September 30, 2008, $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five months ended December 31, 2006, $8,855,000 for the fiscal year ended July 31, 2006 and $6,258,000 for the fiscal year ended July 31, 2005. We anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Given the recent downturn in the economy, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such

securities may be issued without the approval or other consent of our stockholders.

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

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

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

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

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

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

As of September 30, 2008, ProQuest Investments, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 23.2% of our outstanding common stock (assuming exercise of certain warrants held by ProQuest Investments). In addition, Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. As of September 30, 2008, Dr. Rosenwald beneficially owns approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald).

As such, ProQuest Investments, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald□s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the NYSE Alternext, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald or Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. Given the recent downturn in the economy, there can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities. See Risk Factors - We Will Require Significant Capital For Product Development And Commercialization and Our Strategy Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates And We May Require Additional Collaboration Agreements. If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products.

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

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

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of the calendar year 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. 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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. In

addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist™, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist™ in order to complete their review. 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, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. In addition, on October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. However, we have not yet resumed clinical development activity, as we have not yet determined if it is advisable to resume spending significant resources on our development activities. There can be no assurances that we will be able to secure a sufficient amount of additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

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

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

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

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

WE ARE DEPENDENT ON OUR SUPPLIERS.

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

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

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

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

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

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

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

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

WE FACE INTENSE COMPETITION.

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

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

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

LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.

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

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.

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

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

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

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

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

The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal

prosecutions. To market our products outside the U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist, the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. or elsewhere. If the FDA and other regulators do not approve any one or more of our products under development, we will not be able to market such products.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

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

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

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

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

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

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

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

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

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

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of such product candidates. If we fail to successfully develop these relationships or if our

collaboration partners fail to successfully develop or commercialize such product candidates, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana in June 2006. The safety and efficacy of the drug will be based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the trade name Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additi