NOVADEL PHARMA INC
Form S-3
May 26, 2009

As filed with the Securities and Exchange Commission on May 26, 2009

Registration Statement No. 333-

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

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
Chairman, Interim President and Chief Executive Officer and Interim Chief Financial 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 agent 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, 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 large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1][2][3]	Amount of registration fee
Common Stock, par value $0.01 per share [4]	(5)	
Preferred Stock, par value $0.01 per share [6]	(5)	
Debt Securities [7]	(5)	
Warrants [8]	(5)	
Totals	$ 10,500,000	$ 590

(1) The proposed maximum offering price will be determined from time to time by the Registrant in connection with the issuance of securities registered under this Registration Statement.

(2) Estimated solely for purposes of calculating the amount of the registration fee pursuant to Rule 457(o) promulgated under the Securities Act of 1933, as amended.

(3) In no event will the aggregate initial offering price of all securities issued from time to time pursuant to this Registration Statement exceed $10,500,000. Securities registered under this Registration Statement may be sold separately, or together. This total amount also includes such securities as may, from time to time, be issued upon conversion or exchange of securities registered under this Registration Statement, to the extent any such securities are, by their terms, convertible into or exchangeable for other securities.

(4) An indeterminate number of shares of common stock of the Registrant as may be sold from time to time are being registered under this Registration Statement. Also includes such indeterminate number of shares of common stock as may be (a) issued upon conversion, redemption or exchange for any debt securities, preferred stock or other securities that provide for conversion or exchange into common stock, (b) issued upon exercise and settlement of any warrants or (c) issued as a result of stock splits, stock dividends or similar transactions.

(5) Not required to be included pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.

(6) An indeterminate number of shares of preferred stock of the Registrant as may be sold from time to time are being registered under this Registration Statement. Also includes such indeterminate number of shares of preferred stock as may be (a) issued upon conversion, redemption or exchange for any debt securities, preferred stock or other securities that provide for conversion or exchange into preferred stock, (b) issued upon exercise and settlement of any warrants or (c) issued as a result of stock splits, stock dividends or similar transactions.

(7) An indeterminate principal amount of debt securities of the Registrant as may be sold from time to time are being registered under this Registration Statement. If any debt securities of the Registrant are issued at an original issue discount, then the offering price shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed $10,500,000, less the dollar amount of any securities previously issued under this Registration Statement.

(8) An indeterminate number of warrants of the Registrant as may be sold from time to time are being registered under this Registration Statement. Warrants may be exercised to purchase common stock, preferred stock or debt securities.

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 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 contained in this prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated May 26, 2009

PROSPECTUS

$10,500,000
DEBT SECURITIES
WARRANTS
PREFERRED STOCK
COMMON STOCK

NovaDel Pharma Inc. may from time to time offer to sell debt securities, warrants, preferred stock and/or common stock, separately or together in one or more combinations. The debt securities, warrants and preferred stock may be convertible into or exercisable or exchangeable for common stock or preferred stock or other securities of NovaDel Pharma Inc. or any other party identified in the applicable prospectus supplement.

Our common stock is traded on the NYSE AMEX LLC, referred to herein as NYSE AMEX, under the symbol NVD . The last reported sale of our common stock on the NYSE AMEX on May 22, 2009 was $0.27 per share. Our principal offices are located at 25 Minneakoning Road, Flemington, New Jersey 08822. Our telephone number is (908) 782-3431.

The aggregate market value of our outstanding voting and nonvoting common equity held by non-affiliates is $14,500,000. The total amount of debt securities, warrants, preferred stock and common stock will have an initial aggregate offering price of up to $10,500,000, or the equivalent amount in other currencies, currency units or composite currencies.

The securities covered by this prospectus may be offered and sold to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis.

This prospectus describes some of the general terms that may apply to these securities and the general manner in which they may be offered. The specific terms of any securities to be offered, and the specific manner in which they may be offered, will be described in one or more supplements to this prospectus.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. RISKS ASSOCIATED WITH AN INVESTMENT IN OUR SECURITIES WILL BE DESCRIBED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND CERTAIN OF OUR FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION, AS DESCRIBED UNDER THE SECTION ENTITLED RISK FACTORS ON PAGE 29 OF THIS PROSPECTUS. THE PROSPECTUS SUPPLEMENT APPLICABLE TO EACH TYPE OR SERIES OF SECURITIES WE OFFER MAY CONTAIN A DISCUSSION OF ADDITIONAL RISKS APPLICABLE TO AN INVESTMENT IN US AND THE PARTICULAR TYPE OF SECURITIES WE ARE OFFERING UNDER THAT PROSPECTUS SUPPLEMENT.

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 THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is May , 2009

EXPLANATORY NOTE

The prospectus contained herein relates to the general description of debt securities, warrants, preferred stock and common stock issuable by NovaDel Pharma Inc.

To the extent required, the information in the prospectus, including financial information, will be updated at the time of each offering. Upon each such offering, a prospectus supplement to the base prospectus will be filed.

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You should rely only on the information provided in this prospectus and the prospectus supplement, as well as the information incorporated by reference. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus, the prospectus supplement or any documents incorporated by reference is accurate as of any date other than the date of the applicable document.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission, referred to herein as the SEC, using a shelf registration process. Under a shelf registration process, we may issue, in one or more offerings, any combination of senior or subordinated debt securities, warrants, preferred stock or common stock, collectively referred to herein as the securities, up to a total dollar amount of $10,500,000.

Each time we sell these securities we will provide you with a prospectus supplement containing specific information about the terms of each such sale. This prospectus may not be used to sell any of the securities unless accompanied by a prospectus supplement. The prospectus supplement also may add, update or change information in this prospectus. If there is any inconsistency between the information in the prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement. You should read both this prospectus and any prospectus supplement together with additional information described under the heading Where You Can Find More Information; Incorporation of Documents by Reference beginning on page 71 of this prospectus.

Unless otherwise indicated or unless the context otherwise requires, all references in this prospectus to we, us, or similar references mean NovaDel Pharma Inc. and our subsidiaries.

You should rely only on the information contained in this prospectus or in a prospectus supplement or amendment. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. We may offer to sell, and seek offers to buy these securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or a prospectus supplement or amendment or incorporated herein by reference is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of securities.

ABOUT NOVADEL PHARMA INC.

GENERAL

NovaDel Pharma Inc., a Delaware corporation, referred to herein as we , us and our , is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed pharmaceuticals. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have eight patents which have been issued in the U.S. and 64 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing for our product candidates.

Our goal is to become a leading specialty pharmaceutical company that develops and commercializes improved formulations of existing drugs using our patented oral spray technology. We believe that our technology has application to a broad number of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following characteristics:

Significant prescription sales already exist;

Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs; and

Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today s environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

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 product candidates and to market and distribute the final products either internally or with the assistance of strategic partners.

We have had a history of recurring losses, giving rise to an accumulated deficit as of March 31, 2009 of $77.3 million, as compared to $67.2 million as of March 31, 2008. We have had negative cash flow from operating activities of $1.6 million and $4.0 million for the three months ended March 31, 2009 and 2008, respectively. As of March 31, 2009, we had negative working capital of $(2.3) million, as compared to $2.1 million as of March 31, 2008, representing a net decrease in working capital of approximately $4.4 million.

We are seeking to raise additional capital in early 2009 to fund our operations and future development activities through a license agreement or by taking advantage of other strategic opportunities. These opportunities could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. Our ability to fund operations is also dependent on whether ProQuest Investments, or ProQuest, to which we have issued $4.0 million of secured convertible notes in fiscal 2008, consisting of $1.5 million of notes issued in the initial closing on May 30, 2008, the Initial Closing Notes, and $2.5 million of notes issued in the subsequent closing on October 17, 2008, the Subsequent Closing Notes, demands payment under such notes. Given our current level of spending, if ProQuest demands payment under the Initial Closing Notes and the Subsequent Closing Notes, we will not be able to repay the notes in full, unless we are successful prior to that time in securing funds through new strategic partnerships and/or the sale of common stock or other securities. However, if ProQuest demands payment under the Initial Closing Notes and under the Subsequent Closing notes and we are not successful in securing new funds, we will not have sufficient cash on hand to fund operations. If ProQuest fully converts the Initial Closing Notes and Subsequent Closing notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through third quarter 2009. On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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

Since the fourth quarter 2007 and continuing through the first quarter of 2009, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe

that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

Our audited financial statements for the year ended December 31, 2008, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

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

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

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

In addition, as of March 31, 2009, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Amex LLC Company Guide with stockholders equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years; and Section 1003(a)(i) of the NYSE Amex LLC Company Guide with stockholders equity of less than $2,000,000 and losses from continuing operations and net losses in two of our three most recent fiscal years. However, as previously noted, the plan that we submitted to the NYSE Amex LLC on June 13, 2008 reasonably demonstrates our ability to attain a stockholders equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

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

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

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

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

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

Highlights for the year ended December 31, 2008, for the three months ended March 31, 2009 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.

Intellectual Property

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

Other

Announced that we had entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P. for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock, referred to herein as the 2008 Financing.

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 received a notification from NYSE Amex LLC that we were not in compliance with certain of the NYSE Amex LLC continued listing standards. On June 12, 2008, we submitted a plan of compliance to the NYSE Amex LLC for review. On July 30, 2008, NYSE Amex LLC notified us that it had completed its review of our proposed plan of compliance and has determined that we have made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan periods. On January 23, 2009, the NYSE Amex LLC notified us that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex LLC Company Guide. The NYSE Amex LLC is continuing our listing pursuant to an extension, subject to certain conditions.

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

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

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

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

PRODUCT DEVELOPMENT

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

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

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

the scope, rate of progress and expense of our clinical trials and other research and development activities;

results of future clinical trials;

the expense of clinical trials for additional indications;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the expense and timing of regulatory approvals or changes in the regulatory approval process;

the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technologies and market developments; and

the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

	Active Ingredient or Class of Molecule	Indications	Stage of Development	Partner
Approved Products				
NitroMist	**nitroglycerin**	**Angina Pectoris**	**FDA Approved**	
Zolpimist	**zolpidem**	**Insomnia**	**FDA Approved**	
Product Candidates				
Zensana	**ondansetron**	**Nausea/Vomiting**	**Clinical development**	**Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.**
NVD-201	**sumatriptan**	**Migraines**	**Pilot Efficacy study complete**	
Zolpimist	**zolpidem**	**Middle-of-the-Night Awakening**	**Clinical development**	
NVD-301	**midazolam**	**Pre-Procedure Anxiety**	**Preclinical development**	
NVD-401	**sildenafil**	**Erectile Dysfunction**	**Preclinical development**	
NVD-501	**fentanyl**	**Breakthrough Pain**	**Preclinical development**	

NitroMist (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceutical, Inc., or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. Our former contract manufacturer for NitroMist , INyX Pharma, filed for protection under the Chapter 11 bankruptcy laws in 2007, and ceased operations at its facility in Puerto Rico where our product was to be manufactured during 2008. As a result, we selected an alternative contract manufacturer, DPT Laboratories, and are in the process of transferring manufacturing operations to DPT. We are currently investigating strategic partners for this product.

Zolpimist (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hytic marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects, completed in the first half of calendar 2005, suggested that our formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. In October 2006, we announced positive results from a pilot pharmacokinetic study comparing our formulation of Zolpimist to Ambien® tablets. In the study, 10 healthy male volunteers received Zolpimist or Ambien® tablets in 5mg or 10mg doses. For fasting subjects, fifteen minutes after dosing, 80% of subjects using Zolpimist achieved blood concentrations of greater than 20 ng/ml, compared to 33% of subjects in the 5mg Ambien® tablet group and 40% of subjects in the 10mg Ambien® tablet group. The difference between the oral spray groups and tablet groups was statistically significant (p=0.016). Twenty ng/ml is a level generally believed to approximate the lower limit of the therapeutic range for zolpidem. Additionally, drug concentrations were measured at five and ten minutes post-dosing. At these early time points, the oral spray groups achieved drug levels five-to-thirty times greater than subjects in the corresponding tablet groups. These differences were also statistically significant. Zolpimist has the potential to provide patients with the meaningful benefit of faster onset of sleep as compared to existing sleep remedies should future studies validate the already completed Pilot PK study. We submitted the NDA for our zolpidem product candidate in the second half of 2007, and the FDA indicated acceptance of this NDA filing in January 2008. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA in order to complete their review. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist for the short-term treatment of insomnia. We are currently investigating strategic partners for this product.

Zensana (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GlaxoSmithKline, or GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana . Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada, including the development and re-filing

of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana during 2008, and expected to submit a new NDA for Zensana by the end of 2008. However, Par recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana .

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

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

On May 19, 2008, we entered into an agreement with BioAlliance Pharma S.A., whereby BioAlliance acquired the European rights for our ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. We anticipate collaborating with BioAlliance in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product.

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

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan which represents drug absorbed directly across the oral mucosa was

approximately 70% faster with the 20mg NVD-201 than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the NVD-201 than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg NVD-201 appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including multiple sclerosis, spinal cord injury, stroke and cerebral palsy, which leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from

spasticity with a very convenient solution to this serious treatment problem. We were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in view of the higher priority associated with our current product pipeline as described above, we do not anticipate further development of tizanidine oral spray due to commercial and operational priorities.

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

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.

BUSINESS DEVELOPMENT

To date, we have entered into license agreements with (i) Hana Biosciences, for the development and 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 NitroMist , (iii) Manhattan Pharmaceuticals, in connection with propofol, (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs and (v) BioAlliance Pharma SA, for the European rights for Ondansetron oral spray. In addition, we have entered into a sub-license agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana . Lindsay A. Rosenwald, M.D., a stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount BioCapital, Inc., 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. Dr. Rosenwald and Paramount may 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. Through December 31, 2008, Dr. Lindsay Rosenwald beneficially owned approximately 5.2% of our outstanding common stock and was deemed to be our affiliate through that time. However, as of May 1, 2009, Dr. Rosenwald beneficially owned approximately 2.2% of our outstanding common stock and, therefore, would no longer be considered an affiliate of ours.

In July 2007, we entered into a Product Development and Commercialization Sublicense Agreement, or the Sublicense Agreement, with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-

transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana . In connection therewith, Hana Biosciences amended and restated their existing License and Development Agreement, as amended, with us relating to the development and commercialization of Zensana , referred to herein as 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. 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 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, with a fair value of $140,000, that had been acquired by us in connection with execution of the original License Agreement.

Also in July 2007, we and Par agreed to terminate the agreement relating to NitroMist . We are currently investigating strategic partners for the commercialization of NitroMist . During the three months ended September 30, 2007, we recorded $177,000 of revenue to write-off the remaining deferred revenue relating to this agreement.

On May 19, 2008, we and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for our Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. BioAlliance and us anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product. The upfront payment has been included in deferred revenue and is being recognized in income over the term of the agreement (nineteen and one half-years). During the three and twelve months ended December 31, 2008, we recognized $38,000 and $96,000 of income related to this contract, respectively.

We intend to enter into additional license agreements and strategic alliances, including:

- Marketing partners for our NitroMist (nitroglycerine) and Zolpimist (zolpidem tartrate) oral sprays.
- Additional marketing partners and strategic alliances as may be appropriate for the remaining present and future products in our development pipeline.

AGREEMENT WITH PAR PHARMACEUTICAL, INC. AND HANA BIOSCIENCES, INC.

In October 2004, we entered into a license and development agreement pursuant to which we granted to Hana Biosciences an exclusive license to develop and market Zensana , our oral spray version of ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences purchased 400,000 shares of our common stock at a per share price equal to $2.50, a premium of $0.91 per share or $364,000 over the then market value of our common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to us $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share). The fair value of the common stock received from Hana Biosciences was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, we entered into a Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana . In connection therewith, we and Hana Biosciences amended and restated our existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana 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. 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 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, with a fair value of $140,000, that had been acquired by us in connection with execution of the original License Agreement.

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

LICENSE AND SUPPLY AGREEMENT WITH PAR PHARMACEUTICAL, INC.

In July 2004, we entered into a 10-year license and supply agreement with Par, a wholly owned subsidiary of Par Pharmaceutical Companies, Inc., whereby Par has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the U.S. and Canada. The terms of the agreement call for an upfront license fee which was paid to us in July 2004, a milestone payment made to us upon the FDA s acceptance of an NDA for our nitroglycerin lingual spray for review in September 2004, another potential milestone payment if and when the NDA is approved for marketing in the U.S., and double-digit percentage royalties on net sales of the product in the U.S. and Canada. We are responsible for obtaining regulatory approval for the product and for supplying the product to Par.

In July 2007, we and Par agreed to terminate the agreement relating to NitroMist . We are currently investigating strategic partners for the commercialization of NitroMist . During the three months ended September 30, 2007, we recorded $177,000 of revenue to write-off the remaining deferred revenue relating to this agreement.

AGREEMENT WITH MANHATTAN PHARMACEUTICALS, INC.

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain license, milestone and other payments, the first $125,000 of which was received in June 2003. In November 2003, we received $375,000 from Manhattan Pharmaceuticals for license fees. We have included these license fees in deferred revenue and are recognizing these license fees over the 20-year term of the license. In July 2007, Manhattan Pharmaceuticals, our partner for its propofol oral spray product candidate, announced that as part of its change in strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate.

Lindsay A. Rosenwald, M.D., a stockholder of the Company, may be deemed to be an affiliate of Manhattan Pharmaceuticals, Velcera, and Hana Biosciences. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to our agreements with the parties to such agreements from time to time.

AGREEMENT WITH VELCERA PHARMACEUTICALS, INC. (FORMERLY VETCO)

In June 2004, we entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to our propriety oral spray technology in animals. In September 2004, we received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and is being recognized in income over the 20-year term of the agreement. In addition, we received an equity stake of 529,500 shares of common stock in Velcera which did not have a material value. Such investment continues to be carried at its cost

basis of $0 as of December 31, 2008. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement called for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera s Promist platform, which is based on its patented oral spray technology. We may receive additional milestone payments and royalty payments over the 20-year term of the agreement. In November 2007, the common stock of the merged companies began trading on the OTC bulletin board. On March 5, 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause. On October 17, 2008, Velcera announced that it had filed a Form 15 with the SEC, as a result of which Velcera s obligation to file reports with the SEC has terminated.

AGREEMENT WITH BIOALLIANCE PHARMA SA

On May 19, 2008, we and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for our Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. The Company is eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. We and BioAlliance anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product. The upfront payment has been included in deferred revenue and is being recognized in income over the term of the agreement (nineteen and one half-years). During the three months ended March 31, 2009, the Company recognized $38,000 of income related to this contract.

BUSINESS STRATEGY

Strategy

Our goal is to become a leading specialty pharmaceutical company that develops and commercializes improved formulations of existing drugs using our patented oral spray technology. We believe that our technology has application to a broad number of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following characteristics:

Significant prescription sales already exist;

Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs; and

Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today s environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

Products

We currently have six product candidates in our pipeline. One of these product candidates, Zensana , is currently licensed to a marketing partner who will commercialize this product candidate, with us receiving milestone and royalty income from revenue upon product approval. For our NitroMist and Zolpimist products which are approved, we will most likely seek marketing partners to commercialize these product candidates, as their distribution will require significant resources. No current marketing partners exist for these two approved products. For the remainder of our pipeline, we expect to secure marketing partners for these product candidates after we have generated sufficient clinical data to demonstrate the effectiveness of these product candidates. We anticipate that such marketing partners for both our approved and our development products would provide us with milestone payments and royalties based on revenues.

In addition to our existing product candidates, we intend to continue to identify and pursue additional product candidates for development.

PATENTED AND PATENT PENDING DELIVERY SYSTEMS

We have certain patents and pending patent applications for our oral spray delivery system. FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product candidate will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA or other relevant health authority prior to marketability, and the amount of regulatory oversight required by the FDA or other regulatory agencies will also depend on the specific type of drug product for which the delivery system is implemented. Our aerosol and pump spray formulations release drugs in the form of a fine mist into the buccal portion of the mouth for rapid absorption into the bloodstream via the mucosal membranes. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and adherence. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products.

MARKETING AND DISTRIBUTION

To date, we have chosen to license products developed with our technology to other drug companies. We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

We anticipate that promotion of our product candidates, whether conducted by us or by a strategic partner, will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such product candidates. We intend to position our product candidates as alternatives or as line extensions to brand-name products. We believe that to the extent our formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented may be offered to brand-name manufacturers as improved substitute products after patent protection on existing products expire.

In as much as we do not have the financial or other resources to undertake extensive marketing activities, we generally intend to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties. We believe that such third-party arrangements will permit us to maximize the promotion and distribution of pharmaceutical products while minimizing our direct marketing and distribution costs. If we are unable to enter into additional agreements, we may not be able to successfully market our product candidates.

We have not yet determined strategies relating to marketing of our other proposed formulated products; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. As a company, we have no experience in marketing or distribution of our product candidates, and our ability to fund such marketing activities will require us to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

MANUFACTURING

We intend to contract out the manufacturing of our product candidates. Our current facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. We will have to contract out manufacturing and/or invest additional funds in the current facility in order to provide internal manufacturing capability. The manufacture of our pharmaceutical product candidates is subject to cGMP prescribed by the FDA and pre-approval inspections by the

FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1 of our Annual Report on Form 10-K, Business- Raw Materials and Suppliers and Government Regulation.

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

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.

RAW MATERIALS AND 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 and Japan and can be delivered to our manufacturing facility by such suppliers. We intend to enter into arrangements with such third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of our product candidates. Accordingly, we may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact on the manufacturing costs (which will, in turn, have an impact on the cost of our product candidates). To the extent that transactions relating to the purchase of raw materials involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with our product candidates may be available only from sole source suppliers. Although we believe that we will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. A failure 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 could have a material adverse effect on our ability to manufacture formulated products.

Development and regulatory approval of our product candidates 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 specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

GOVERNMENT REGULATION

FDA approval process

In the United States, pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the

results of all preclinical, clinical and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently $1,178,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently $65,030 per product and $392,700 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by FDA for three additional months to consider certain new information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with good clinical practices, or GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication proposed for marketing.

After FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not

challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will 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. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing 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. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, 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, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

We expect that the majority of our product candidates in development will require the filing of 505(b)(2) NDAs because, although such products contain previously approved chemical entities, we or our licensees may seek to make new claims regarding therapeutic effects or lessened side effects, or both.

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana in June 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, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. On July 31, 2007, we entered into a Product Development and

Commercialization Sublicense Agreement with Hana Biosciences and Par Pharmaceutical, 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. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana during 2008, and expected to submit a new NDA for Zensana by the end of 2008. However, in November 2008, Par announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies to determine the work necessary to complete Zensana s development and proceed with an NDA submission. Because we rely upon Par to develop and file the NDA for Zensana we can give no assurances that Par will be able to re-file the NDA for Zensana , if at all, and ultimately receive final FDA approval. The safety and efficacy of the drug is based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us, Hana Biosciences, and/or Par for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences previously announced that it had not received any objections related to these patent certifications.

Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute

has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

COMPETITION

The markets which we intend to enter are characterized by intense competition, often from organizations which are larger and/or better capitalized than us. We will be competing against established pharmaceutical companies which currently market 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 proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

We are aware of several companies that are selling or developing oral spray products. Sciele Pharma Inc. (formerly First Horizon Pharmaceutical Corporation), headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an air propelled dispensing system (our nitroglycerin lingual spray is a propellant based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist device. This product was approved in Ecuador, certain Middle Eastern countries, and India. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Generex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that develop and/or market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the UK, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis, or MS, and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Sosei Co. Ltd. is conducting Phase III clinical studies for its Fentanyl sublingual spray (AD923), an opioid analgesic for the

treatment of cancer breakthrough pain. Insys Therapeutics Inc. is developing a Fentanyl sublingual spray for breakthrough cancer pain in opioid-tolerant patients.

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.

PATENTS AND PROTECTION OF PROPRIETARY INFORMATION

We have applied for U.S. and foreign patent protection for our buccal spray delivery systems which are the primary focus of our development activities as well as for our delayed contact allergy topical formulations. Eight U.S. patents, three Canadian patents and sixty-one European patents have been issued. The sixty-one patents in Europe consist of four unique patents which have been issued in up to seventeen different countries. We have over ninety patent applications pending in the U.S. and overseas. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims, however, that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our licensees and potential development candidates to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

Buccal Nonpolar Sprays. On April 12, 1996, we filed an application with the U.S. Patent and Trademark Office, or the USPTO, with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty, or the PCT, (PCT Publication No. WO 97/38663) for the above-subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, with claims directed to the above subject matter. On April 16, 2003, European Patent No. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs (i.e., anti-histamines, steroid hormones, non-steroidal anti-inflammatories, benzodiazepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. We have filed a divisional application based on this European patent. On April 17, 2007 this application issued to us as European Patent No. 1 275 374 with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics This European patent has been validated in the U.K., Germany, France, Italy, Belgium, Switzerland/Lichtenstein, Sweden, the Netherlands, Spain, and Greece, so that there is patent protection in these countries. No opposition has been filed to this application and the time for filing any opposition has expired.

With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. The Canadian Patent Office granted the application on December 27, 2005 as Canadian Patent No. 2,252,050. The allowed claims are similar to those granted by the European Patent Office.

Buccal Polar Sprays. On April 12, 1996, we filed an application with the USPTO with claims directed to propellant free buccal polar spray compositions containing certain amounts of a polar solvent and certain classes of drugs (i.e., non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepams, and anti-depressants), as well as specific drugs within those classes. The application also contained claims to soft-bite gelatin capsules containing such drugs. A continuation-in-part, or CIP, application was filed directed to this subject matter before the original application was allowed to go abandoned. The USPTO initially rejected the claims in the CIP application. We deleted the claims from this application (including the soft-bite capsule claims) and replaced them with claims directed to methods of using the above-described propellant free buccal polar spray compositions to administer the drugs. On August 29, 2000, U.S. Patent No. 6,110,486 was issued to us with claims directed to the above-described methods of administering the drugs. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the PCT (PCT Publication No. WO 97/38662) for the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter.

On February 2, 2005, European Patent No. 0 910 339 was granted to us with claims directed to use of polar solvent containing pump sprays containing similar drugs to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there was patent protection in these countries. In November 2005, Akzo Nobel N.V. filed a successful opposition against this patent in the European Patent Office alleging lack of inventive step. We have decided not to file any appeal in connection with this opposition. As a result, the European Patent is no longer in force.

With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. On February 10, 2006, the Canadian Patent Office issued a Notice of Allowance for this application. On October 10, 2006, Canadian Patent No. 2,252,038 was granted to us with claims directed to the use of a pharmacologically active compound selected from the group consisting of non-steroidal anti-inflammatories, anti-histamines, steroid

hormones, benzodiazepines, and anti-depressants for the preparation of a buccal aerosol pump spray composition for being absorbed through the oral mucosa.

Buccal Nonpolar Spray for Nitroglycerin. On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

On February 21, 1997, we filed a PCT application (PCT Publication No. WO 97/38687) directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive.

In October 1998, we entered the national phase in Canada. We filed a request for examination on February 7, 2002. The Canadian Patent Office issued a second office action to us dated July 11, 2005. We responded to the office action on January 11, 2006. As a result, Canadian Patent No. 2,251,564 was granted to us on January 9, 2007, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant.

In November 1998, we entered the national phase in Europe. European Patent No. 0 927 032 was granted to us on April 16, 2003, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries.

Buccal Polar/Nonpoloar Sprays or Capsules. On October 1, 1997, we filed a PCT application (PCT Publication No. WO 99/16417) designating a large number of countries including the U.S., directed to the buccal sprays and soft-bite capsules. The application included claims directed to: (A) a buccal spray composition containing either (1) a polar solvent with certain classes of drugs, as well as specific drugs in those classes with or without a propellant or (2) a non-polar solvent with or without a propellant with certain classes of drugs, as well as specific drugs in those classes; (B) buccal spray composition containing a non-polar solvent, a flavoring agent and certain classes of drugs; and (C) methods of administering these drugs using the buccal spray compositions. The application also contained claims to soft-bite gelatin capsules containing such drugs. This application differs from the first three applications, discussed above, in that the claimed compositions include different classes of drugs from those described in the first three applications. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

On March 29, 2000, we entered the national phase in the U.S. by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions.

Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application was issued to us as U.S. Patent No. 6,998,110 with claims directed to methods of administering a biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, sleep inducers, antiasthmatics, antiemetics, antivirals, histamine H-2 receptor antagonists, barbiturates, prostaglandins, or bronchial dilators using the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs. This patent expires on October 1, 2017. Another application has been filed directed to additional formulations relating to U.S. Patent No. 6,998,110. The second divisional application was

issued to us as U.S. Patent No. 6,676,931. This patent expires on October 1, 2017. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs and formulations that were not included in the claims of U.S. Patent No. 6,676,931.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has been received from the Canadian Patent Office and we have responded to that office action.

Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. An office action rejecting the pending claims has been received from the Japanese Patent Office. We have demanded a trial in response to that office action. In addition, we are in the process of filing a divisional application in Japan claiming priority to this application.

Based on the above-identified PCT application, we also entered the national phase in Europe in April 2000. The European application includes claims directed to propellant free buccal spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. We have filed three applications related to this application in Europe. The first application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant and certain classes of drugs as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. This application was granted to us on April 18, 2007, as European Patent No. 1 295 536 with claims directed to a buccal spray composition including a propellant, a non-polar solvent, and one of the following active compounds: biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, antivirals, sleep inducers, antihistamines, antiemetics, histamine H-2 receptor antagonists, barbiturates, prostoglandins, and bronchial dilators selected from the group consisting of terbutaline, and theophylline. A divisional application has been filed claiming priority from this patent. The second application included claims directed to propellant free buccal spray compositions containing certain amounts of a non-polar solvent and certain classes of drugs, as well as specific drugs in those classes. The third application included claims directed to a buccal spray composition containing certain amounts of a polar solvent, a propellant and certain classes of drugs, as well as specific drugs in those classes. Each of the above-identified European applications is currently being prosecuted.

Furthermore, in August 2002, we filed a number of U.S. patent applications directed to buccal spray compositions containing certain classes of drugs as well as specific drugs for treating particular types of disorders. In August 2003, we filed PCT applications related to these U.S. applications. We have subsequently filed corresponding applications in Europe, Japan and Canada for the subject matter for a majority of these CIP applications.

From these U.S. patent applications, we have been granted U.S. Patent No. 6,969,508 with claims directed to methods for administering an effective amount of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof using a buccal spray composition containing a polar solvent and a propellant. We have also been granted U.S. Patent No. 6,977,070 with claims directed to methods for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of acetylcholinesterase inhibitors, nerve impulse inhibitors, anti-cholinergics, anti-convulsants, anti-psychotics, anxiolytic agents, dopamine metabolism inhibitors, agents to treat post stroke sequelae, neuroprotectants, agents to treat Alzheimer s disease, neurotransmitters, neurotransmitter agonists, sedatives, agents for treating attention deficit disorder, agents for treating narcolepsy, central adregenic antagonists, anti-depression agents, agents for treating Parkinson s disease, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, and mixtures there of using a buccal spray containing a polar solvent and a propellant.

In addition, in September 2003, we filed a number of U.S. patent applications directed to buccal spray compositions containing specific drugs. We have subsequently filed corresponding applications in Europe, Japan, Canada, Israel and Korea for the subject matter a majority of these CIP applications.

Stable Hydroalcoholic Oral Spray Formulations and Methods. On April 19, 2007, we filed an application with the USPTO with claims directed to hydroalcoholic spray compositions and methods. The application was published on October 25, 2007, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On April 19, 2007 we also filed a corresponding PCT application (PCT Publication No. WO 2007/123955) to the above noted subject matter. On October 30, 2008, the International Bureau issued an International Preliminary Report on Patentability alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

Based on the above-identified PCT application, we entered the national phase in Canada, Europe and Japan in October 2008.

Anti-Migraine Oral Spray Formulations and Methods. On July 27, 2007 we filed an application with the USPTO with claims directed to compositions comprising a selective 5-hydroxytryptamine receptor subtype agonist and methods of treatment. The application was published on February 7, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On July 27, 2007 we also filed a corresponding PCT application (PCT Publication No. W0 2008/013929) to the above noted subject matter. On April 25, 2008, the International Searching Authority issued a Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

Based on the above-identified PCT application, we entered the national phase in Canada, Europe and Japan in January 2009.

Stable Anti-Nausea Oral Spray Formulations and Methods. On December 21, 2007 we filed an application with the USPTO with claims directed to formulations containing a selective 5-hydroxytryptamine receptor antagonist and methods of treatment. The application was published on July 17, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On December 21, 2007 we also filed a corresponding PCT application (PCT Publication No. W0 2008/079295) to the above noted subject matter. On May 1, 2008, the International Searching Authority issued a Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive. We will be making decisions regarding national stage entries based on this PCT application by June 2009.

Anti-Insomnia Compositions and Methods. On May 12, 2008 we filed an application with the USPTO with claims directed to administering an anti-insomnia composition by buccal spray for transmucosal absorption to a patient. The application was published on November 13, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On May 12, 2008 we also filed a corresponding PCT application (PCT Publication No. W0 2008/141264) to the above noted subject matter. On July 30, 2008, the International Searching Authority issued a Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive. We will be making decisions regarding national stage entries based on this PCT application in November 2009.

Antihistamine Syrup and Ointment. On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts

of a polar or non-polar solvent. On May 21, 2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method. This patent expires on November 10, 2017.

General Comment with Respect to Entering the National Phase for Each of the Foregoing PCT Applications. In addition to our patents and patent applications in the U.S., we are interested in entering the national phase and obtaining patent protection in Europe, Japan and Canada. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications in Canada, Japan and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed $100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

EMPLOYEES

As of May 16, 2009, we had 7 total employees, all of whom were full-time employees.

CORPORATE INFORMATION

We were incorporated in Delaware in 1982. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431. We maintain a website at http://www.novadel.com (this is not a hyperlink; you must visit this website through an Internet browser). Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the Commission. You may read and copy any document we file with the Commission at the Commission s public reference rooms at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Our Commission filings are also available to the public from the Commission s Website at http://www.sec.gov. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to sratoff@novadel.com or contact Steven B. Ratoff, our Chairman, Interim President and Chief Executive Officer and Interim Chief Financial Officer at 25 Minneakoning Road, Flemington, New Jersey, 08822 or at 908-782-3431.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus, any prospectus supplement and in the documents incorporated by reference herein constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements frequently, but not always, use the words may , intends , plans , believes , anticipates or expects or similar words and may include statements concerning our strategies, goals a plans. All forward-looking statements are management s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company s financial condition; the progress of the Company s research and development; inadequate supplies of drug substance and drug product; timely obtaining sufficient patient enrollment in the Company s clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company s ability to obtain additional required financing to fund its research programs; the Company s ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the U.S. Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company s clinical trials and the marketing of the Company s products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company s internal controls and procedures; and other factors discussed under the caption Risk Factors included in any prospectus supplement and under the caption Risks Related to Our Business in our Annual Report on Form 10-K for the year ended December 31, 2008, which is incorporated by reference into the Registration Statement of which this prospectus forms a part.

The following documents, among others, describe these assumptions, risks, uncertainties, and other factors. You should read and interpret any forward-looking statements together with these documents:

- the risk factors contained in any prospectus supplement under the caption Risk Factors ;
- our most recent annual report on Form 10-K, including the sections entitled Business , Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations ;
- our quarterly reports on Form 10-Q; and
- our other SEC filings.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus, any prospectus supplement or in any document incorporated by reference in this prospectus might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date of this prospectus, the date of any prospectus supplement or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to us are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, and in any documents incorporated in this report by reference.

RISKS RELATED TO OUR BUSINESS

Our Auditors Have Expressed Substantial Doubt About Our Ability To Continue As A Going Concern.

Our audited financial statements for the year ended December 31, 2008, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, such capital formation activities may not be available or may not be available on reasonable terms. Our condensed financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We Will Require Significant Additional Capital To Fund Our Operations.

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

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

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

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

- further delay, scale-back or eliminate some or all of our research and product development programs;

license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;

attempt to sell our company;

cease operations; or

declare bankruptcy.

We are seeking to raise additional capital in 2009 to fund our operations and future development activities through a license agreement or by taking advantage of other strategic opportunities. These opportunities could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. Our ability to fund operations is also dependent on whether ProQuest Investments, or ProQuest, to which we have issued $4.0 million of secured convertible notes in fiscal 2008, consisting of $1.5 million of notes issued in the initial closing on May 30, 2008, the Initial Closing Notes, and $2.5 million of notes issued in the subsequent closing on October 17, 2008, the Subsequent Closing Notes, demands payment under such notes. The convertible notes issued in the Initial Closing matured on November 30, 2008 and, in the Subsequent Closing, matured on April 17, 2009. On November 30, 2008, with respect to the Initial Closing, and on April 17, 2009, with respect to the Subsequent Closing, the noteholders did not either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, inclusive of accrued and unpaid interest at a rate of 10% per annum. However, on April 29, 2009, we remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes. The convertible notes are secured by all of our assets, other than certain excluded assets.

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

We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007 and continuing throughout 2008, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations. We may choose to raise additional capital in 2009 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. There can be no assurance that such capital will be available to us on favorable terms, or at all.

We Will Require Significant Capital For Product Development And Commercialization In The Near Term.

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. Given the recent downturn in the economy, we can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us. Since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities.

Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. The convertible notes are secured by all of our assets, other than certain excluded assets. During the second quarter of 2008, we also entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000.

Given our current level of spending, if ProQuest demands payment under the Initial Closing Notes and the Subsequent Closing Notes, we will not be able to repay the notes in full, unless we are successful prior to that time in securing funds through new strategic partnerships and/or the sale of common stock or other securities. The convertible notes issued in the Initial Closing matured on November 30, 2008 and, in the Subsequent Closing, matured on April 17, 2009. On November 30, 2008, with respect to the Initial Closing, and on April 17, 2009, with respect to the Subsequent Closing, the noteholders did not either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, inclusive of accrued and unpaid interest at a rate of 10% per annum. However, on April 29, 2009, we remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes. The convertible notes are secured by all of our assets, other than certain excluded assets.

In addition, we have agreed to pay ProQuest, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

We may also determine that it is appropriate to increase development activities on our product candidate pipeline, which activities have been significantly reduced since the fourth quarter of 2007 and continuing throughout 2008, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products. An increase in development activities would significantly increase cash outflows and thereby require additional funding in order to sustain operations. We may choose to raise additional capital in 2009 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. There can be no assurance that such capital will be available to us on favorable terms, or at all.

We Are A Pre-Commercialization Company, Have A Limited Operating History And Have Not Generated Any Revenues From The Sale Of Products To Date.

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist for the short-term treatment of insomnia. We are currently investigating strategic partners for both NitroMist and Zolpimist . We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future. Since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities.

On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. In addition, we have agreed to pay ProQuest, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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 March 31, 2009 of approximately $77,328,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $2,139,000 for the three months ended March 31, 2009, $9,586,000 for the year ended December 31, 2008, $16,963,000 for the year ended December 31, 2007, $3,805,000 for the five months ended December 31, 2006 and $10,084,000 for the fiscal year ended July 31, 2006. Additionally, we have reported negative cash flows from operations of approximately $1,575,000 for the three months ended March 31, 2009, $5,533,000 for the year ended December 31, 2008, $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five months ended December 31, 2006 and $8,855,000 for the fiscal year ended July 31, 2006. We anticipate that, even with our limited research and development activities, we could incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders.

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Given the recent downturn in the economy, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

Our Technology Platform Is Based Solely On Our Proprietary Drug Delivery Technology. Our Ongoing Clinical Trials For Certain Of Our Product Candidates May Be Delayed, Or Fail, Which Will Harm Our Business.

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

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

the number of clinical sites;

the size of the patient population;

the proximity of patients to the clinical sites;

the eligibility criteria for the study;

the existence of competing clinical trials; and

the existence of alternative available products.

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

There Are Certain Interlocking Relationships And Potential Conflicts Of Interest.

As of May 1, 2009, ProQuest Investments, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 38.1% of our outstanding common stock (assuming exercise of certain warrants held by ProQuest Investments). As such, ProQuest Investments may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Chairman, Interim President and Chief Executive Officer and Interim Chief Financial Officer, has served as a venture partner with ProQuest Investments since December 2004, although he has no authority for investment decisions by ProQuest Investments.

Through December 31, 2008, Dr. Lindsay Rosenwald beneficially owned approximately 5.2% of our outstanding common stock and was deemed to be our affiliate through that time. As an affiliate, Dr. Rosenwald had the ability to designate an individual to serve on our Board of Directors, or the Board, and had exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell was a designee of Dr. Rosenwald s, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald, and in addition Dr. Rosenwald has ceased to be an affiliate of ours, as a result of his disposition of certain shares of our common stock and the expiration of certain warrants to purchase our common stock. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the NYSE Amex LLC, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences, each of which company has entered into a license agreement with us. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. As of May 1, 2009, Dr. Rosenwald beneficially owned approximately 2.2% of our outstanding common stock and, therefore, would no longer be considered an affiliate.

Our Business And Revenue Is Dependent On The Successful Development Of Our Products.

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. Since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance Pharma S.A., as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000. On April 29, 2009, we remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued in 2008.

In addition, we have agreed to pay ProQuest, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10%

of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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 In The Near Term and Our Strategy Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates And We May Require Additional Collaboration Agreements. If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products.

Some Of Our Product Candidates Are In Early Stages Of Clinical Development And Some Are In Preclinical Testing, Which May Affect Our Ability Or The Time We Require To Obtain Necessary Regulatory Approvals.

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

We Do Not Have Commercially Available Products.

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of the calendar year 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist for the short-term treatment of insomnia. We are currently investigating strategic partners for both NitroMist and Zolpimist . Our partner for Zensana , Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana . Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us. Since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of

2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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

We Have Not Completed Product Development.

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist to us as part of Par s strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist , our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist in order to complete their review. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist for the short-term treatment of insomnia. We are currently investigating strategic partners for both NitroMist and Zolpimist . Our partner for Zensana , Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana . Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations. Furthermore, since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. On May 30, 2008, we closed on the initial portion of such financing for $1,475,000 of convertible notes and warrants. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result

of which we received an immediate non-refundable license fee of $3,000,000. On October 17, 2008, we closed on the remaining portion of convertible note financing, and received gross proceeds of $2,525,000.

In addition, we have agreed to pay ProQuest, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by ProQuest for the shares that we are not able to register for resale in connection with subsequent closing, referred to herein as subsequent registrable shares. Such liquidated damages equal $12,703 for each 30-day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by ProQuest, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). On April 29, 2009, the Company remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued during 2008.

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

We Do Not Have Direct Consumer Marketing Experience.

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

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

We Must Comply With Good Manufacturing Practices.

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

We Are Dependent On Our Suppliers.

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a

written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX USA, Ltd., whereby Inyx shall manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. On July 3, 2007, INyX, our manufacturer for our NitroMist product candidate, announced it filed for protection under the Chapter 11 bankruptcy laws. In June 2008, the trustees for INyX informed us that the facility in Manati, Puerto Rico would cease operations at the end of July 2008. As a result, we selected an alternative manufacturer for NitroMist , DPT Laboratories Inc, and are in the process of transferring manufacturing operations to DPT.

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

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

Failure To Achieve And Maintain Effective Internal Controls In Accordance With Section 404 Of The Sarbanes-Oxley Act Of 2002 Could Have A Material Adverse Effect On Our Business And Operating Results. In Addition, Current And Potential Stockholders Could Lose Confidence In Our Financial Reporting, Which Could Have A Material Adverse Effect On Our Stock Price.

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

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

Compliance With Changing Regulation Of Corporate Governance And Public Disclosure May Result In Additional Expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission, or SEC, and NYSE Amex, or NYSE Amex rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by

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

We Face Intense Competition.

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

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

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

Limited Product Liability Insurance Coverage May Affect Our Business.

We may be exposed to potential product liability claims by end-users of our products. Although we obtain product liability insurance per contractual obligations, before the commercialization of any of our product candidates, we cannot guarantee such insurance will be sufficient to cover all possible liabilities to which we may be exposed. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a

condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our product candidates, which could have a material adverse effect on us.

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 .

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

If We Cannot Protect Our Intellectual Property, Other Companies Could Use Our Technology In Competitive Products. If We Infringe The Intellectual Property Rights Of Others, Other Companies Could Prevent Us From Developing Or Marketing Our Products.

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

defend our patents and otherwise prevent others from infringing on our proprietary rights;

protect our trade secrets; and

operate without infringing upon the proprietary rights of others, both in the U.S. and in other countries.

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

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

To the extent that the Section 505(b)(2) applicant is relying on the FDA s findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has

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

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

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

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

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

Even If We Obtain Patents To Protect Our Products, Those Patents May Not Be Sufficiently Broad And Others Could Compete With Us.

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

office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

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

Intellectual Property Rights Of Third Parties Could Limit Our Ability To Market Our Products.

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

If We Cannot Meet Requirements Under Our License Agreements, We Could Lose The Rights To Our Products.

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

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

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

We Rely On Confidentiality Agreements That Could Be Breached And May Be Difficult To Enforce.

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

they will breach these agreements;

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

our competitors will independently discover our proprietary information and trade secrets.

We Are Dependent On Existing Management And Board Members.

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

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

RISKS RELATED TO OUR COMMON STOCK

We Received Notice From The NYSE Amex LLC That We Failed To Comply With Certain Of Its Continued Listing Standards, Which May Result In A Delisting Of Our Common Stock From The Exchange.

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

In addition, as of December 31, 2008, we are no longer in compliance with Section 1003(a)(ii) of the NYSE Amex Company Guide with stockholders equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years; and Section 1003(a)(i) of the NYSE Amex Company Guide with stockholders equity of less than $2,000,000 and losses from continuing operations and net losses in two of our three most recent fiscal years. However, as previously noted, the plan we submitted to the NYSE Amex on June 13, 2008 reasonably demonstrates our ability to attain a stockholders equity of $6,000,000 or above by no later than November 16, 2009, which will also address the deficiencies noted in Section 1003(a)(ii) and Section 1003(a)(i).

On January 23, 2009, we were notified by the NYSE Amex that they had granted us an extension until April 17, 2009 to regain compliance with Section 1003 (a)(iv) of the NYSE Amex Company Guide. Our deadline to regain compliance with Section 1003(a)(i), (ii) and (iii) remains November 16, 2009. On April 30, 2009, the

Company received a letter from NYSE, Amex LLC that the Company s listing on the exchange continues to be extended to the targeted date of November 16, 2009.

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

On May 6, 2008, we entered into a binding Securities Purchase Agreement, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes at maturity. On April 29, 2009, we remitted $1.0 million to ProQuest Investments and related entities against the $4.0 million of convertible notes issued in 2008. During the second quarter of 2008, we entered into a European partnership for our ondansetron oral spray with BioAlliance, as a result of which we received an immediate non-refundable license fee of $3,000,000. We may also enter into additional agreements during 2009. The combined amounts of such agreements are not sufficient to cure the deficiency in net worth position as of December 31, 2007 and December 31, 2008. We are currently reviewing several alternative sources of capital, which if successfully implemented may allow us to satisfy the NYSE Amex listing standards. There can be no assurances that we will be able to obtain any additional capital, or on terms favorable to us, or that we will be able to maintain our continued listing on the NYSE Amex.

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

We Are Influenced By Current Stockholders, Officers And Directors.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of May 1, 2009, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 39.9% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest Investments has the ability to exert significant influence over matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

The Market Price Of Our Stock And Our Earnings May Be Adversely Affected By Market Volatility.

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

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior

governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;

changes in the U.S. or foreign regulatory policy during the period of product development;

developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;

announcements of technological innovations by us or our competitors;

announcements of new products or new contracts by us or our competitors;

actual or anticipated variations in our operating results due to the level of development expenses and other factors;

changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

conditions and trends in the pharmaceutical and other industries;

new accounting standards; and

the occurrence of any of the risks set forth in these Risk Factors and other reports, including this prospectus and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the NYSE Amex since May 11, 2004 under the symbol NVD. Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the twelve-month period ended March 31, 2009, the closing price of our common stock has ranged from $0.06 to $0.46. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve-month period ended December 31, 2008, the average daily trading volume in our common stock was approximately 407,210 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

Because The Average Daily Trading Volume Of Our Common Stock Is Low, The Ability To Sell Our Shares In The Secondary Trading Market May Be Limited.

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

We Likely Will Issue Additional Equity Securities, Which Will Dilute Current Stockholders Share Ownership.

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

Penny Stock Regulations May Impose Certain Restrictions On Marketability Of Our Securities.

The SEC has adopted regulations which generally define a penny stock to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain

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

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

control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;

manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;

boiler room practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

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

Additional Authorized Shares Of Our Common Stock And Preferred Stock Available For Issuance May Adversely Affect The Market.

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of May 1, 2009, there were 60,911,374 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants, or the conversion of our convertible notes. As of May 1, 2009, we had outstanding stock options and warrants to purchase approximately 27.1 million shares of common stock, the exercise prices of which range between $0.21 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 27.1 million shares of common stock as of May 1, 2009 noted above.

On October 17, 2008, an additional $2,525,000 of secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock. We issued 6,446,809 warrants, which have an exercise price of $0.294 per share, and are included in the total outstanding stock options and warrants to purchase approximately 27.1 million shares of common stock as of May 1, 2009 noted above.

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

Plan	Shares Authorized	Options Outstanding at May 1, 2009	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000		Plan Closed
1997 Stock Option Plan	500,000	50,000		Plan Closed
1998 Stock Option Plan	3,400,000	1,789,000	1,315,000	
2006 Equity Incentive Plan	6,000,000	4,552,000	518,000	
Non-Plan	n/a	581,000		
Total	**10,400,000**	**7,012,000**	**1,833,000**	

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

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

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

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

Shares Eligible For Future Sale May Adversely Affect The Market.

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

substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

Limitation On Director/Officer Liability.

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

We Have No History Of Paying Dividends On Our Common Stock.

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

Provisions Of Our Certificate Of Incorporation And Delaware Law Could Deter A Change Of Our Management Which Could Discourage Or Delay Offers To Acquire Us.

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

Sales Of Large Quantities Of Our Common Stock, Including Those Shares Issuable In Connection With Private Placement Transactions, Could Reduce The Price Of Our Common Stock.

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

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

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

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

In April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,168 shares of our common stock. The sale of the shares

of common stock and warrants resulted in gross proceeds to us of approximately $11.8 million, prior to offering expenses.

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

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

The depth and liquidity of the markets for our common stock;

Investor perception of us and the industry in which we participate; and

General economic and market conditions.

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

As of May 1 2009, we have 60,911,374 shares of common stock issued and outstanding and approximately 27.1 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In addition, and not included in the above, on May 6, 2008, we entered into a binding Securities Purchase Agreement with the Purchasers, as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants. In connection with this agreement, $1,475,000 of secured convertible notes and accompanying warrants were funded on May 30, 2008. The convertible notes are convertible into 5,000,000 shares of our common stock. We issued 3,000,000 warrants, which have an exercise price of $0.369 per share, and are included in the total outstanding stock options and warrants to purchase approximately 27.1 million shares of common stock noted above. On October 17, 2008, $2,525,000 of additional secured convertible notes and accompanying warrants were funded. The convertible notes are convertible into 10,744,681 shares of our common stock, and an additional 6,446,809 warrants were issued with an exercise price of $0.294 per share, which warrants are included in the 27.1 million shares of common stock for options and warrants noted above. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

The Securities Issued In Our December 2006 Private Placement And Our 2008 Private Placement Are Restricted Securities.

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

We Have Broad Discretion As To The Use Of The Proceeds From The 2008 Private Placement And May Use The Proceeds In A Manner With Which You Disagree.

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

We May Incur Significant Costs From Class Action Litigation Due To Our Expected Stock Volatility.

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

The Uncertainty Created By Current Economic Conditions And Possible Terrorist Attacks And Military Responses Thereto Could Materially Adversely Affect Our Ability To Sell Our Products, And Procure Needed Financing.

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

Our Inability To Manage The Future Growth That We Are Attempting To Achieve Could Severely Harm Our Business.

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

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

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

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

We May Be Obligated, Under Certain Circumstances, To Pay Liquidated Damages To Holders Of Our Common Stock.

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

With respect to the subsequent closing of the 2008 private placement, we agreed to file a registration statement with the SEC to register the resale of 17,978,724 shares of common stock issuable pursuant to the 2008 private placement, referred to herein as the subsequent registrable shares, within 30 days of the related closing. Also, we agreed to respond to all SEC comment letters as promptly as reasonably possible and to use our best efforts to have the registration statement declared effective within 90 days of the related closing. However, we were unable to register 9,044,649 of the subsequent registrable shares in accordance with the rules and regulations of the SEC. Therefore, we are filing the registration statement with the SEC to register the resale of 8,934,075 subsequent registrable shares issuable pursuant to the 2008 private placement. There is no guarantee that the SEC will declare the registration statement effective. In connection with our reduction of subsequent registrable shares being registered on the registration statement, we have agreed with the purchasers to pay, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by the purchasers for the shares that we are not able to register for resale under the registration statement. Such liquidated damages equal $12,703 for each 30 day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments may not exceed 10% of the aggregate purchase price paid by the purchasers, or $127,030. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note).

DESCRIPTION OF THE SECURITIES WE MAY OFFER

We may issue, in one or more offerings, any combination of senior or subordinated debt securities, warrants, preferred stock or common stock.

This prospectus contains a summary of the general terms of the various securities that we may offer. The prospectus supplement relating to any particular securities offered will describe the specific terms of the securities, which may be in addition to or different from the general terms summarized in this prospectus. The summary in this prospectus and in any prospectus supplement does not describe every aspect of the securities and is subject to and qualified in its entirety by reference to all applicable provisions of the documents relating to the securities offered. These documents are or will be filed as exhibits to or incorporated by reference in the registration statement.

In addition, the prospectus supplement will set forth the terms of the offering, the initial public offering price and estimated net proceeds to us. Where applicable, the prospectus supplement will also describe any material United States federal income tax considerations relating to the securities offered and indicate whether the securities offered are or will be listed on any securities exchange.

DEBT SECURITIES

Please note that in this section entitled Debt Securities, references to holders mean those who own debt securities registered in their own names, on the books that we or the trustee maintains for this purpose, and not those who own beneficial interests in debt securities registered in street name or in debt securities issued in book-entry form through one or more depositaries. Owners of beneficial interests in the debt securities should read the section below entitled Book-Entry Procedures and Settlement .

General

The debt securities offered by this prospectus will be our unsecured obligations and will be either senior or subordinated debt. We will issue senior debt under a senior debt indenture, and we will issue subordinated debt under a subordinated debt indenture. We sometimes refer to the senior debt indenture and the subordinated debt indenture individually as an indenture and collectively as the indentures. The indentures will be filed with the SEC

prior to effectiveness of this registration statement and will be exhibits to the registration statement of which this prospectus forms a part. You can obtain copies of the indentures by following the directions outlined in Where You Can Find More Information; Incorporation of Documents by Reference , or by contacting the applicable indenture trustee.

A form of each debt security, reflecting the particular terms and provisions of a series of offered debt securities, will be filed with the SEC subsequent to the time of the applicable offering as exhibits to a Current Report on Form 8-K which, upon filing with the SEC, will be incorporated by reference into the registration statement of which this prospectus forms a part.

The following briefly summarizes the material provisions of the indentures and the debt securities, other than pricing and related terms disclosed for a particular issuance in an accompanying prospectus supplement. The specific terms of the debt securities of a particular series will be disclosed in the prospectus supplement relating to that series. Wherever particular sections or defined terms of the applicable indenture are referred to, the statement in this prospectus is qualified by that reference. Prior to investing in our debt securities, you should read the particular terms of that series of debt securities described in the applicable prospectus supplement. You should also carefully read the more detailed provisions of the applicable indenture relating to that series.

The trustee under each of the senior debt indenture and the subordinated debt indenture will be the trustee named in the prospectus supplement.

The indentures provide that our unsecured senior or subordinated debt securities may be issued in one or more series, with different terms, in each case as we authorize from time to time. We also have the right to reopen a previous issue of a series of debt securities by issuing additional debt securities of such series.

Types of Debt Securities

We may issue fixed or floating rate debt securities.

Fixed rate debt securities will bear interest at a fixed rate described in the prospectus supplement. This type includes zero coupon debt securities, which bear no interest and are often issued at a price lower than the principal amount. Material federal income tax consequences and other special considerations applicable to any debt securities issued at a discount will be described in the applicable prospectus supplement.

Upon the request of the holder of any floating rate debt security, the calculation agent will provide the interest rate then in effect for that debt security, and, if determined, the interest rate that will become effective on the next interest reset date. The calculation agent s determination of any interest rate, and its calculation of the amount of interest for any interest period, will be final and binding in the absence of manifest error.

All percentages resulting from any interest rate calculation relating to a debt security will be rounded upward or downward, as appropriate, to the next higher or lower one hundred-thousandth of a percentage point. All amounts used in or resulting from any calculation relating to a debt security will be rounded upward or downward, as appropriate, to the nearest cent, in the case of U.S. dollars, or to the nearest corresponding hundredth of a unit, in the case of a currency other than U.S. dollars, with one-half cent or one-half of a corresponding hundredth of a unit or more being rounded upward.

In determining the base rate that applies to a floating rate debt security during a particular interest period, the calculation agent may obtain rate quotes from various banks or dealers active in the relevant market, as described in the prospectus supplement. Those reference banks and dealers may include the calculation agent itself and its affiliates, as well as any underwriter, dealer or agent participating in the distribution of the relevant floating rate debt securities and its affiliates.

Information in the Prospectus Supplement

The prospectus supplement for any offered series of debt securities will describe the following terms, as applicable:

the title;

whether the debt is senior or subordinated;

the total principal amount offered;

the percentage of the principal amount at which the debt securities will be sold and, if applicable, the method of determining the price;

the maturity date or dates;

whether the debt securities are fixed rate debt securities or floating rate debt securities;

if the debt securities are fixed rate debt securities, the yearly rate at which the debt security will bear interest, if any, and the interest payment dates;

if the debt security is an original issue discount debt security, the yield to maturity;

if the debt securities are floating rate debt securities, the interest rate basis; any applicable index currency or maturity, spread or spread multiplier or initial, maximum or minimum rate; the interest reset, determination, calculation and payment dates; and the day count used to calculate interest payments for any period;

the date or dates from which any interest will accrue, or how such date or dates will be determined, and the interest payment dates and any related record dates;

if other than in U.S. Dollars, the currency or currency unit in which payment will be made;

any provisions for the payment of additional amounts for taxes;

the denominations in which the currency or currency unit of the securities will be issuable if other than denominations of $1,000 and integral multiples thereof;

the terms and conditions on which the debt securities may be redeemed at our option;

any of our obligations to redeem, purchase or repay the debt securities at the option of a holder upon the happening of any event and the terms and conditions of redemption, purchase or repayment;

the names and duties of any co-trustees, depositaries, authenticating agents, calculation agents, paying agents, transfer agents or registrars for the debt securities;

any material covenants to which the debt securities are subject;

any material provisions of the applicable indenture described in this prospectus that do not apply to the debt securities; and

any other specific terms of the debt securities.

The terms on which a series of debt securities may be convertible into or exchangeable for our other securities or any other entity will be set forth in the prospectus supplement relating to such series. Such terms will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. The terms may include provisions pursuant to which the number of other securities to be received by the holders of such series of debt securities may be adjusted.

We will issue the debt securities only in registered form. As currently anticipated, debt securities of a series will trade in book-entry form, and global notes will be issued in physical, or paper, form, as described below under Book-Entry Procedures and Settlement . Unless otherwise provided in the accompanying prospectus supplement, we intend to issue debt securities denominated in U.S. dollars and only in denominations of $1,000 and integral multiples thereof.

The prospectus supplement relating to offered securities denominated in a foreign or composite currency will specify the denomination of the offered securities.

The debt securities may be presented for exchange, and debt securities other than a global security may be presented for registration of transfer, at the principal corporate trust office of the trustee named in the prospectus supplement. Holders will not have to pay any service charge for any registration of transfer or exchange of debt securities, but we may require payment of a sum sufficient to cover any tax or other governmental charge payable in connection with such registration of transfer.

Payment and Paying Agents

Distributions on the debt securities other than those represented by global notes will be made in the designated currency against surrender of the debt securities at the principal corporate trust office of the trustee named in the prospectus supplement. Payment will be made to the registered holder at the close of business on the record date for such payment. Interest payments will be made at the principal corporate trust office of the trustee named in the prospectus supplement, or by a check mailed to the holder at his registered address. Payments in any other manner will be specified in the prospectus supplement.

Calculation Agents

Calculations relating to floating rate debt securities and indexed debt securities will be made by the calculation agent, an institution that we appoint as our agent for this purpose. The initial calculation agent will be identified in the prospectus supplement. We may appoint a different institution to serve as calculation agent from time to time after the original issue date of the debt security without your consent and without notifying you of the change.

Senior Debt

We will issue senior debt securities under the senior debt indenture. Senior debt will rank on an equal basis with any other unsecured debt of ours except subordinated debt.

Subordinated Debt

We will issue subordinated debt securities under the subordinated debt indenture. Subordinated debt will rank subordinated and junior in right of payment, to the extent set forth in the subordinated debt indenture and the applicable prospectus supplement, to our senior debt.

Covenants

The material covenants relating to a series of debt securities offered by this prospectus will be disclosed in the prospectus supplement relating to such series of debt securities.

Limitations on Mergers and Sales of Assets

The indentures provide that we will not merge or consolidate or transfer or lease all or substantially all of our property or assets, and another person may not transfer or lease all or substantially all of its property or assets to us, unless:

either (1) we are the continuing corporation, or (2) the successor corporation, if other than us, is a U.S. corporation and expressly assumes by supplemental indenture the obligations evidenced by the securities issued pursuant to the indenture; and

immediately after the transaction, there would not be any default in the performance of any covenant or condition of the indenture.

Modification of the Indentures

Under the indentures, we and the relevant trustee can enter into supplemental indentures to establish the form and terms of any new series of debt securities, consistent with the terms of the indenture, without obtaining the consent of any holder of debt securities.

We and the trustee may, with the consent of the holders of at least a majority in aggregate principal amount of the debt securities of a series, modify the applicable indenture or the rights of the holders of the securities of such series.

No such modification may, however, without the consent of each holder of an affected security:

extend the fixed maturity of any such securities;

reduce the rate or change the time of payment of interest on such securities;

reduce the principal amount of such securities or the premium, if any, on such securities;

change any obligation of ours to pay additional amounts;

reduce the amount of the principal payable on acceleration of any securities issued originally at a discount;

adversely affect the right of repayment or repurchase at the option of the holder;

adversely affect the right, if any, to convert or exchange such debt security;

reduce or postpone any sinking fund or similar provision;

change the currency or currency unit in which any such securities are payable or the right of selection thereof;

impair the right to sue for the enforcement of any such payment on or after the maturity of such securities;

reduce the percentage of securities referred to above whose holders need to consent to the modification or a waiver without the consent of such holders;

change any obligation of ours to maintain an office or agency; or

change other provisions of such security as may be specified in the prospectus supplement relating to the debt securities of that series.

Notwithstanding the preceding, without the consent of any holder of outstanding securities, we and the trustee may amend or supplement the indentures:

to cure any ambiguity, defect or inconsistency;

to provide for uncertificated securities in addition to or in place of certificated securities;

to provide for the assumption of our obligations to holders of any debt security in the case of a merger or consolidation or sale of all or substantially all of our property or assets;

to make any change that would provide any additional rights or benefits to the holders of securities or that does not adversely affect the legal rights under the indenture of any such holder;

to comply with requirements of the SEC in order to effect or maintain the qualification of an indenture under the Trust Indenture Act;

to conform the text of the indentures to any provision of the description of debt securities in a prospectus supplement; and

to provide for the issuance of additional securities in accordance with the limitations set forth in the indenture.

The consent of holders is not necessary under the indentures to approve the particular form of any proposed amendment. It is sufficient if such consent approves the substance of the proposed amendment.

Defaults

Each indenture provides that events of default regarding any series of debt securities will be:

- our failure to pay required interest on any debt security of such series for 30 days;
- our failure to pay principal, premium or sinking fund, if any, on any debt security of such series when due;
- our failure to make any required scheduled installment payment for 30 days on debt securities of such series;
- our failure to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days, or within such other time period as may be specified in the applicable indenture, after we receive notice from the debenture trustee or holders of at least 25%, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of the applicable series;
- our failure to pay beyond any applicable grace period, or the acceleration of, indebtedness in excess of any dollar amount specified in the prospectus supplement;
- certain events of bankruptcy or insolvency, whether voluntary or not; and
- any other event of default provided with respect to debt securities of that series in accordance with provisions of the indenture related to the issuance of such debt securities.

If an event of default regarding debt securities of any series issued under the indentures should occur and be continuing, either the trustee or the holders of 25% in the principal amount of outstanding debt securities of such series may declare each debt security of that series due and payable. We are required to file annually with the trustee a statement of an officer as to the fulfillment by us of our obligations under the indenture during the preceding year.

No event of default regarding one series of debt securities issued under an indenture is necessarily an event of default regarding any other series of debt securities.

Holders of a majority in principal amount of the outstanding debt securities of any series will be entitled to control certain actions of the trustee under the indentures and to waive past defaults regarding such series. The trustee generally cannot be required by any of the holders of debt securities to take any action, unless one or more of such holders shall have provided to the trustee reasonable security or indemnity.

If an event of default occurs and is continuing regarding a series of debt securities, the trustee may use any sums that it holds under the relevant indenture for its own reasonable compensation and expenses incurred prior to paying the holders of debt securities of such series.

Before any holder of any series of debt securities may institute action for any remedy, except payment on such holder s debt security when due, the holders of not less than 25% in principal amount of the debt securities of that series outstanding must request the trustee to take action. Holders must also offer and give the satisfactory security and indemnity against liabilities incurred by the trustee for taking such action.

Discharge and Defeasance

Unless otherwise indicated in an applicable prospectus supplement, each indenture provides that we may satisfy and discharge obligations thereunder with respect to the debt securities of any series by delivering to the trustee for cancellation all outstanding debt securities of the series or depositing with the trustee, after the outstanding debt securities have become due and payable, or will become due and payable within one year or will be called for redemption within one year, cash sufficient to pay at stated maturity or redemption all of the outstanding debt securities of the series and all other sums payable under the indenture with respect to the series.

Except as may otherwise be set forth in an accompanying prospectus supplement, after we have deposited with the trustee, cash or government securities, in trust for the benefit of the holders sufficient to pay the principal of, premium, if any, and interest on the debt securities of such series when due, and satisfied certain other conditions, including receipt of an opinion of counsel that holders will not recognize taxable gain or loss for federal income tax purposes, then:

- we will be deemed to have paid and satisfied our obligations on all outstanding debt securities of such series, which is known as defeasance and discharge; or
- we will cease to be under any obligation, other than to pay when due the principal of, premium, if any, and interest on such debt securities, relating to the debt securities of such series, which is known as covenant defeasance.

When there is a defeasance and discharge, the applicable indenture will no longer govern the debt securities of such series, we will no longer be liable for payments required by the terms of the debt securities of such series and the holders of such debt securities will be entitled only to the deposited funds. When there is a covenant defeasance, however, we will continue to be obligated to make payments when due if the deposited funds are not sufficient.

Conversion and Exchange Rights

If specified in the applicable prospectus supplement, the debt securities of a series may be convertible into or exchangeable for our common stock or other securities. We will describe in the applicable prospectus supplement, among other things, the conversion or exchange rate or price and any adjustments thereto, the conversion or exchange period or periods, provisions as to whether conversion or exchange will be mandatory, at our option or at the option of the holders of that series of debt securities and provisions affecting conversion or exchange in the event of the redemption of that series of debt securities.

Governing Law

Unless otherwise stated in the prospectus supplement, the debt securities and the indentures will be governed by New York law.

Concerning the Trustee under the Indentures

We may have and may continue to have banking and other business relationships with the trustee named in the prospectus supplement, or any subsequent trustee, in the ordinary course of business.

Form, Exchange, Registration and Transfer

Unless otherwise provided in a prospectus supplement, we intend to issue debt securities only in registered global form.

You may have your debt securities broken into more debt securities of smaller denominations or combined into fewer debt securities of larger denominations, as long as the total principal amount is not changed and so long as the denominations are in multiples of $1,000 or such other amount as may be specified in the applicable prospectus supplement. This is called an exchange.

You may exchange or transfer debt securities at the office of the trustee. The trustee acts as our agent for registering debt securities in the names of holders and transferring debt securities. We may appoint another entity or perform this role ourselves. The entity performing the role of maintaining the list of registered holders is called the security registrar. It will also perform transfers. You will not be required to pay a service charge to transfer or exchange debt securities, but you may be required to pay for any tax or other governmental charge associated with the exchange or transfer. The transfer or exchange will only be made if the security registrar is satisfied with your proof of ownership.

If the debt securities are redeemable and we redeem less than all of the debt securities of a particular series, we may block the transfer or exchange of those debt securities during the period beginning 15 days before the day we mail the notice of redemption and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers or exchanges of debt securities selected for redemption, except that we will continue to permit transfers and exchanges of the unredeemed portion of any debt security being partially redeemed.

WARRANTS

Please note that in this section references to holders mean those who own warrants registered in their own names, on the books that we or our agent maintain for this purpose, and not those who own beneficial interests in warrants registered in street name or in warrants issued in book-entry form through one or more depositaries. Owners of beneficial interests in the warrants should read the section below entitled Book-Entry Procedures and Settlement .

General

We may offer warrants separately or together with our debt or equity securities.

We may issue warrants in such amounts or in as many distinct series as we wish. This section summarizes terms of the warrants that apply generally to all series. Most of the financial and other specific terms of your warrant will be described in the prospectus supplement. Those terms may vary from the terms described here.

The warrants of a series will be issued under a separate warrant agreement to be entered into between us and one or more banks or trust companies, as warrant agent, as set forth in the prospectus supplement. A form of each warrant agreement, including a form of warrant certificate representing each warrant, reflecting the particular terms and provisions of a series of offered warrants, will be filed with the SEC at the time of the offering and incorporated by reference in the registration statement of which this prospectus forms a part. You can obtain a copy of any form of warrant agreement when it has been filed by following the directions outlined in Where You Can Find More Information; Incorporation of Documents by Reference or by contacting the applicable warrant agent.

The following briefly summarizes the material provisions of the warrant agreements and the warrants. As you read this section, please remember that the specific terms of your warrant as described in the prospectus supplement will supplement and, if applicable, may modify or replace the general terms described in this section. You should read carefully the prospectus supplement and the more detailed provisions of the warrant agreement and the warrant certificate, including the defined terms, for provisions that may be important to you. If there are differences between the prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements made in this section may not apply to your warrant.

Types of Warrants

We may issue debt warrants or equity warrants. A debt warrant is a warrant for the purchase of our debt securities on terms to be determined at the time of sale. An equity warrant is a warrant for the purchase or sale of our equity securities. We may also issue warrants for the purchase or sale of, or whose cash value is determined by reference to the performance, level or value of, one or more of the following: securities of one or more issuers, including those issued by us and described in this prospectus or debt or equity securities issued by third parties; a currency or currencies; a commodity or commodities; and other financial, economic or other measure or instrument, including the occurrence or non-occurrence of any event or circumstances, or one or more indices or baskets of these items.

Information in the Prospectus Supplement

The prospectus supplement will contain, where applicable, the following information about the warrants:

the specific designation and aggregate number of, and the price at which we will issue, the warrants;

the currency or currency unit with which the warrants may be purchased and in which any payments due to or from the holder upon exercise must be made;

the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;

whether the exercise price may be paid in cash, by the exchange of warrants or other securities or both, and the method of exercising the warrants;

whether the warrants will be settled by delivery of the underlying securities or other property or in cash;

whether and under what circumstances we may cancel the warrants prior to their expiration date, in which case the holders will be entitled to receive only the applicable cancellation amount, which may be either a fixed amount or an amount that varies during the term of the warrants in accordance with a schedule or formula;

whether the warrants will be issued in global or non-global form;

the identities of the warrant agent, any depositaries and any paying, transfer, calculation or other agents for the warrants;

any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed;

whether the warrants are to be sold separately or with other securities, and if the warrants are to be sold with the securities of another company or other companies, certain information regarding such company or companies; and

any other terms of the warrants.

No holder of a warrant will, as such, have any rights of a holder of the debt securities, equity securities or other warrant property purchasable under or in the warrant, including any right to receive payment thereunder.

Additional Information in the Prospectus Supplement for Debt Warrants

In the case of debt warrants, the prospectus supplement will contain, where appropriate, the following additional information:

the designation, aggregate principal amount, currency and terms of the debt securities that may be purchased upon exercise of the debt warrants; and

the designation, terms and amount of debt securities, if any, to be issued together with each of the debt warrants and the date, if any, after which the debt warrants and debt securities will be separately transferable.

No Limit on Issuance of Warrants

The warrant agreements will not limit the number of warrants or other securities that we may issue.

Modifications

We and the relevant warrant agent may, without the consent of the holders, amend each warrant agreement and the terms of each issue of warrants, for the purpose of curing any ambiguity or of correcting or supplementing any defective or inconsistent provision, or in any other manner that we may deem necessary or desirable and that will not adversely affect the interests of the holders of the outstanding unexercised warrants in any material respect.

We and the relevant warrant agent also may, with the consent of the holders of at least a majority in number of the outstanding unexercised warrants affected, modify or amend the warrant agreement and the terms of the warrants. No such modification or amendment may, without the consent of each holder of an affected warrant:

reduce the amount receivable upon exercise, cancellation or expiration;

shorten the period of time during which the warrants may be exercised;

otherwise materially and adversely affect the exercise rights of the beneficial owners of the warrants; or

reduce the percentage of outstanding warrants whose holders must consent to modification or amendment of the applicable warrant agreement or the terms of the warrants.

Merger and Similar Transactions Permitted; No Restrictive Covenants or Events of Default

The warrant agreements will not restrict our ability to merge or consolidate with, or sell our assets to, another firm or to engage in any other transactions. If at any time there is a merger or consolidation involving us or a sale or other disposition of all or substantially all of our assets, the successor or assuming company will be substituted for us, with the same effect as if it had been named in the warrant agreement and in the warrants. We will be relieved of any further obligation under the warrant agreement or warrants, and, in the event of any such merger, consolidation, sale or other disposition, we as the predecessor corporation may at any time thereafter be dissolved, wound up or liquidated.

The warrant agreements will not include any restrictions on our ability to put liens on our assets, including our interests in our subsidiaries, nor will they provide for any events of default or remedies upon the occurrence of any events of default.

Warrant Agreements Will Not Be Qualified under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Enforceability of Rights by Beneficial Owner

Each warrant agent will act solely as our agent in connection with the issuance and exercise of the applicable warrants and will not assume any obligation or relationship of agency or trust for or with any registered holder of or owner of a beneficial interest in any warrant. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant certificate, including any duty or responsibility to initiate any proceedings at law or otherwise or to make any demand upon us.

Holders may, without the consent of the applicable warrant agent, enforce by appropriate legal action, on their own behalf, their right to exercise their warrants, to receive debt securities, in the case of debt warrants, and to receive payment, if any, for their warrants, in the case of universal warrants.

Governing Law

Unless otherwise stated in the prospectus supplement, the warrants and each warrant agreement will be governed by New York law.

PREFERRED STOCK

Our certificate of incorporation authorizes 1,000,000 shares of preferred stock, $0.001 par value per share. As of May 22, 2009, none of our preferred stock are issued and outstanding. The preferred stock may be issued from time to time in one or more series, with such distinctive serial designations, rights and preferences as shall be determined by the board of directors.

The following briefly summarizes the material terms of our preferred stock, other than pricing and related terms disclosed for a particular issuance in an accompanying prospectus supplement. You should read the particular terms of any series of preferred stock we offer which will be described in more detail in the prospectus supplement prepared for such series, together with the more detailed provisions of our certificate of incorporation and the certificate of designations relating to each particular series of preferred stock, for provisions that may be important

to you. The certificate of designations relating to a particular series of preferred stock offered by way of an accompanying prospectus supplement will be filed with the SEC at the time of the offering and incorporated by reference in the registration statement of which this prospectus forms a part. You can obtain a copy of this document by following the directions outlined in Where You Can Find More Information; Incorporation of Documents by Reference. The prospectus supplement will also state whether any of the terms summarized below do not apply to the series of preferred stock being offered.

General

Under our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series, and to establish from time to time a series of preferred stock with the following terms specified:

the number of shares to be included in the series;

the designation, powers, preferences and rights of the shares of the series; and

the qualifications, limitations or restrictions of such series, except as otherwise stated in the certificate of incorporation.

Prior to the issuance of any series of preferred stock, our board of directors will adopt resolutions creating and designating the series as a series of preferred stock and the resolutions will be filed in a certificate of designations as an amendment to the certificate of incorporation. The term board of directors includes any duly authorized committee.

The rights of holders of the preferred stock offered may be adversely affected by the rights of holders of any shares of preferred stock that may be issued in the future, provided that the future issuances are first approved by the holders of the class(es) of preferred stock adversely affected. The board of directors may cause shares of preferred stock to be issued in public or private transactions for any proper corporate purpose. Examples of proper corporate purposes include issuances to obtain additional financing in connection with acquisitions or otherwise, and issuances to our officers, directors and employees pursuant to benefit plans or otherwise. Shares of preferred stock we issue may have the effect of rendering more difficult or discouraging an acquisition of us deemed undesirable by our board of directors.

The preferred stock will be, when issued, fully paid and nonassessable. Holders of preferred stock will not have any preemptive or subscription rights to acquire more of our stock.

We will name the transfer agent, registrar, dividend disbursing agent and redemption agent for shares of each series of preferred stock in the prospectus supplement relating to such series.

Rank

Unless otherwise specified for a particular series of preferred stock in an accompanying prospectus supplement, each series will rank on an equal basis with each other series of preferred stock, and prior to the common stock, as to dividends and distributions of assets.

Dividends

Holders of each series of preferred stock will be entitled to receive cash dividends, when, as and if declared by our board of directors out of funds legally available for dividends. The rates and dates of payment of dividends will be set forth in the prospectus supplement relating to each series of preferred stock. Dividends will be payable to holders of record of preferred stock as they appear on our books on the record dates fixed by the board of directors. Dividends on any series of preferred stock may be cumulative or noncumulative.

We may not declare, pay or set apart for payment dividends on the preferred stock unless full dividends on any other series of preferred stock that ranks on an equal or senior basis have been paid or sufficient funds have been set apart for payment for:

all prior dividend periods of the other series of preferred stock that pay dividends on a cumulative basis; or

the immediately preceding dividend period of the other series of preferred stock that pay dividends on a noncumulative basis.

Partial dividends declared on shares of preferred stock and any other series of preferred stock ranking on an equal basis as to dividends will be declared pro rata. A pro rata declaration means that the ratio of dividends declared per share to accrued dividends per share will be the same for both series of preferred stock.

Similarly, we may not declare, pay or set apart for payment non-stock dividends or make other payments on the common stock or any other of our stock ranking junior to the preferred stock until full dividends on the preferred stock have been paid or set apart for payment for:

all prior dividend periods if the preferred stock pays dividends on a cumulative basis; or

the immediately preceding dividend period if the preferred stock pays dividends on a noncumulative basis.

Conversion and Exchange

The prospectus supplement for any series of preferred stock will state the terms, if any, on which shares of that series are convertible into or exchangeable for shares of our common stock or other securities.

Redemption

If so specified in the applicable prospectus supplement, a series of preferred stock may be redeemable at any time, in whole or in part, at our option or at the option of the holder thereof and may be mandatorily redeemed.

Any partial redemptions of preferred stock will be made in a way that our board of directors decides is equitable.

Unless we default in the payment of the redemption price, dividends will cease to accrue after the redemption date on shares of preferred stock called for redemption and all rights of holders of such shares will terminate except for the right to receive the redemption price.

Liquidation Preference

Upon our voluntary or involuntary liquidation, dissolution or winding up, holders of each series of preferred stock will be entitled to receive distributions upon liquidation in the amount set forth in the prospectus supplement relating to such series of preferred stock, plus an amount equal to any accrued and unpaid dividends. Such distributions will be made before any distribution is made on any securities ranking junior relating to preferred stock in liquidation, including common stock.

If the liquidation amounts payable relating to the preferred stock of any series and any other securities ranking on a parity regarding liquidation rights are not paid in full, the holders of the preferred stock of such series and such other securities will share in any such distribution of our available assets on a ratable basis in proportion to the full liquidation preferences. Holders of such series of preferred stock will not be entitled to any other amounts from us after they have received their full liquidation preference.

Voting Rights

The holders of shares of our preferred stock will have no voting rights, except:

as otherwise stated in the prospectus supplement;

as otherwise stated in the certificate of designations establishing such series; and

as required by applicable law.

COMMON STOCK

Under our certificate of incorporation, as amended to date, we are authorized to issue up to 200,000,000 shares of common stock, $0.001 par value per share. At May 1, 2009, approximately 60,911,374 shares of common stock were issued and outstanding. The following description of our common stock, certificate of incorporation and bylaws are only summaries, and we encourage you to review complete copies of these documents. You can obtain copies of these documents by following the directions outlined in Where You Can Find More Information; Incorporation of Documents by Reference .

Dividends, Voting Rights and Liquidation

Each stockholder of record is entitled to one vote for each outstanding share of our common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. After satisfaction of the dividend rights of holders of any preferred stock, holders of common stock are entitled to any dividend declared by our board out of funds legally available for that purpose. After the payment of liquidation preferences to holders of any preferred stock, holders of common stock are entitled to receive, on a pro rata basis, all our remaining assets available for distribution to stockholders in the event of our liquidation, dissolution or winding up. Holders of common stock do not have any preemptive right to become subscribers or purchasers of additional shares of any class of our capital stock. The rights, preferences and privileges of holders of common stock are subject to, and may be injured by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Transfer Agent and Registrar

American Stock Transfer and Trust Company is the transfer agent and registrar for our common stock.

Delaware Law and Certain Certificate of Incorporation and By-Law Provisions

The provisions of Delaware law and of our certificate of incorporation and by-laws discussed below could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or the best interests of NovaDel.

Business Combinations. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to specified exceptions, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation s voting stock.

Limitation of Liability; Indemnification. Our certificate of incorporation contains provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate, to the extent legally permissible, a director s liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director s duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law. The limitation of liability described above does not alter the liability of our directors and officers under federal securities laws. Furthermore, our certificate of incorporation contains provisions to indemnify our directors and officers to the fullest extent permitted by the General Corporation Law of Delaware. These provisions do not limit or eliminate our right or the right of any shareholder of ours to seek non-monetary relief, such as an injunction or rescission in the event of a breach by a director or an officer of his duty of care to us. We believe that these provisions assist us in attracting and retaining qualified individuals to serve as directors.

BOOK-ENTRY PROCEDURES AND SETTLEMENT

Most offered securities will be book-entry, or global, securities. Upon issuance, all book-entry securities will be represented by one or more fully registered global securities, without coupons. Each global security will be deposited with, or on behalf of, The Depository Trust Company or DTC, a securities depository, and will be registered in the name of DTC or a nominee of DTC. DTC will thus be the only registered holder of these securities.

Purchasers of securities may only hold interests in the global securities through DTC if they are participants in the DTC system. Purchasers may also hold interests through a securities intermediary banks, brokerage houses and other institutions that maintain securities accounts for customers that has an account with DTC or its nominee. DTC will maintain accounts showing the security holdings of its participants, and these participants will in turn maintain accounts showing the security holdings of their customers. Some of these customers may themselves be securities intermediaries holding securities for their customers. Thus, each beneficial owner of a book-entry security will hold that security indirectly through a hierarchy of intermediaries, with DTC at the top and the beneficial owner s own securities intermediary at the bottom.

The securities of each beneficial owner of a book-entry security will be evidenced solely by entries on the books of the beneficial owner s securities intermediary. The actual purchaser of the securities will generally not be entitled to have the securities represented by the global securities registered in its name and will not be considered the owner under the applicable indenture, the declaration of trust or other applicable governing documents relating to the security. In most cases, a beneficial owner will also not be able to obtain a paper certificate evidencing the holder s ownership of securities. The book-entry system for holding securities eliminates the need for physical movement of certificates. However, the laws of some jurisdictions require some purchasers of securities to take physical delivery of their securities in definitive form. These laws may impair the ability to transfer book-entry securities.

A beneficial owner of book-entry securities represented by a global security may exchange the securities for definitive, or paper, securities only if:

DTC is unwilling or unable to continue as depositary for such global security and we do not appoint a qualified replacement for DTC within 90 days; or

we in our sole discretion decide to allow some or all book-entry securities to be exchangeable for definitive securities in registered form.

Unless we indicate otherwise, any global security that is exchangeable will be exchangeable in whole for definitive securities in registered form, with the same terms and of an equal aggregate principal amount. Definitive securities will be registered in the name or names of the person or persons specified by DTC in a written instruction to the registrar of the securities. DTC may base its written instruction upon directions that it receives from its participants.

In this prospectus, for book-entry securities, references to actions taken by security holders will mean actions taken by DTC upon instructions from its participants, and references to payments and notices of redemption to security holders will mean payments and notices of redemption to DTC as the registered holder of the securities for distribution to participants in accordance with DTC s procedures.

DTC is a limited purpose trust company organized under the laws of the State of New York, a member of the Federal Reserve System, a clearing corporation within the meaning of the New York Uniform Commercial Code and a clearing agency registered under section 17A of the Securities Exchange Act of 1934. The rules applicable to DTC and its participants are on file with the SEC.

Neither we nor any trustee or underwriter will have any responsibility or liability for any aspect of the records relating to, or payments made on account of, beneficial ownership interest in the book-entry securities or for maintaining, supervising or reviewing any records relating to the beneficial ownership interests.

Clearstream and Euroclear

Links may be established among DTC, Clearstream Banking, societe anonyme, Luxembourg (Clearstream Banking SA) and Euroclear (two international clearing systems that perform functions similar to those that DTC performs in the U.S.), to facilitate the initial issuance of book-entry securities and cross-market transfers of book-entry securities associated with secondary market trading.

Although we understand that DTC, Clearstream Banking SA and Euroclear have agreed to the procedures provided below in order to facilitate transfers, they are under no obligation to perform such procedures, and the procedures may be modified or discontinued at any time.

Clearstream Banking SA and Euroclear will record the ownership interests of their participants in much the same way as DTC, and DTC will record the aggregate ownership of each of the U.S. agents of Clearstream Banking SA and Euroclear, as participants in DTC.

When book-entry securities are to be transferred from the account of a DTC participant to the account of a Clearstream Banking SA participant or a Euroclear participant, the purchaser must send instructions to Clearstream Banking SA or Euroclear through a participant at least one business day prior to settlement. Clearstream Banking SA or Euroclear, as the case may be, will instruct its U.S. agent to receive book-entry securities against payment. After settlement, Clearstream Banking SA or Euroclear will credit its participant s account. Credit for the book-entry securities will appear on the next day (European time).

Because settlement is taking place during New York business hours, DTC participants can employ their usual procedures for sending book-entry securities to the relevant U.S. agent acting for the benefit of Clearstream Banking SA or Euroclear participants. The sale proceeds will be available to the DTC seller on the settlement date. Thus, to the DTC participant, a cross-market transaction will settle no differently than a trade between two DTC participants.

When a Clearstream Banking SA or Euroclear participant wishes to transfer book-entry securities to a DTC participant, the seller must send instructions to Clearstream Banking SA or Euroclear through a participant at least one business day prior to settlement. In these cases, Clearstream Banking SA or Euroclear will instruct its U.S. agent to transfer the book-entry securities against payment. The payment will then be reflected in the account of the Clearstream Banking SA or Euroclear participant the following day, with the proceeds back-valued to the value date (which would be the preceding day, when settlement occurs in New York). If settlement is not completed on the intended value date (i.e., the trade fails), proceeds credited to the Clearstream Banking SA or Euroclear participant s account would instead be valued as of the actual settlement date.

We may issue, in one or more offerings, any combination of senior or subordinated debt securities, warrants, preferred stock or common stock.

This prospectus contains a summary of the general terms of the various securities that we may offer. The prospectus supplement relating to any particular securities offered will describe the specific terms of the securities, which may be in addition to or different from the general terms summarized in this prospectus. The summary in this prospectus and in any prospectus supplement does not describe every aspect of the securities and is subject to and qualified in its entirety by reference to all applicable provisions of the documents relating to the securities offered. These documents are or will be filed as exhibits to or incorporated by reference in the registration statement.

In addition, the prospectus supplement will set forth the terms of the offering, the initial public offering price and estimated net proceeds to us. Where applicable, the prospectus supplement will also describe any material United States federal income tax considerations relating to the securities offered and indicate whether the securities offered are or will be listed on any securities exchange.

USE OF PROCEEDS

Unless otherwise set forth in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities we offer by this prospectus for general corporate purposes, which may include, among other things:

- additions to working capital;
- the redemption or repurchase of outstanding equity and debt securities;
- the repayment of indebtedness; and
- the expansions of our business through internal growth or acquisitions.

We may raise additional funds from time to time through equity or debt financing, including borrowings under credit facilities, to finance our business and operations.

PLAN OF DISTRIBUTION

We may sell our securities from time to time through underwriters, dealers or agents or directly to purchasers, in one or more transactions at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. We may use these methods in any combination.

By Underwriters

We may use an underwriter or underwriters in the offer or sale of our securities:

If we use an underwriter or underwriters, the offered securities will be acquired by the underwriters for their own account.

We will include the names of the specific managing underwriter or underwriters, as well as any other underwriters, the amounts underwritten by each underwriter, and the terms of the transactions, including the compensation the underwriters and dealers will receive, in the prospectus supplement.

The underwriters will use this prospectus and the prospectus supplement to sell our securities.

We may also sell securities pursuant to one or more standby agreements with one or more underwriters in connection with the call, redemption or exchange of a specified class or series of any of our outstanding securities. In a standby agreement, the underwriter or underwriters would agree either:

to purchase from us up to the number of shares of common stock that would be issuable upon conversion or exchange of all the shares of the class or series of our securities at an agreed price per share of common stock; or

to purchase from us up to a specified dollar amount of offered securities at an agreed price per offered security, which price may be fixed or may be established by formula or other method and which may or may not relate to market prices of our common stock or any other outstanding security.

The underwriter or underwriters may also agree, if applicable, to convert or exchange any securities of the class or series held or purchased by the underwriter or underwriters into or for our common stock or other security.

The underwriter or underwriters may assist in the solicitation of conversions or exchanges by holders of the class or series of securities.

By Dealers

We may use a dealer to sell our securities.

If we use a dealer, such person, as principal, will sell our securities to the dealer.

The dealer will then resell our securities to the public at varying prices that the dealer will determine at the time it sells our securities.

We will include the name of the dealer and the terms of our transactions with the dealer in the prospectus supplement.

By Agents

We may designate agents to solicit offers to purchase our securities.

We will name any agent involved in offering or selling our securities and any commissions that we will pay to the agent in the prospectus supplement.

Unless indicated otherwise in the prospectus supplement, our agents will act on a best efforts basis for the period of their appointment.

An agent may be deemed to be underwriters under the Securities Act of any of our securities that they offer or sell.

By Delayed Delivery Contracts

We may authorize our agents and underwriters to solicit offers by certain institutions to purchase our securities at the public offering price under delayed delivery contracts.

If we use delayed delivery contracts, we will disclose that we are using them in the prospectus supplement and will tell you when payment will be demanded and securities delivered under the delayed delivery contracts.

These delayed delivery contracts will be subject only to the conditions set forth in the prospectus supplement.

We will indicate in the prospectus supplement the commission that underwriters and agents soliciting purchases of our securities under delayed delivery contracts will be entitled to receive.

We may directly solicit offers to purchase our securities, and we may directly sell our securities to institutional or other investors, including our affiliates. We describe the terms of our direct sales in the prospectus supplement. We may also sell our securities upon the exercise of rights which we may issue.

General Information

Underwriters, dealers and agents that participate in the distribution of our securities may be underwriters as defined in the Securities Act, and any discounts or commissions they receive and any profit they make on the resale of the offered securities may be treated as underwriting discounts and commissions under the Securities Act. Any underwriters or agents will be identified and their compensation described in a prospectus supplement. We may indemnify agents, underwriters, and dealers against certain civil liabilities, including liabilities under the Securities Act, or make contributions to payments they may be required to make relating to those liabilities. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

Each series of securities offered by this prospectus may be a new issue of securities with no established trading market. Any underwriters to whom securities offered by this prospectus are sold by us for public offering and sale may make a market in the securities offered by this prospectus, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of the trading market for any securities offered by this prospectus.

Representatives of the underwriters through whom our securities are sold for public offering and sale may engage in over-allotment, stabilizing transactions, syndicate short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Stabilizing transactions permit bids to purchase the offered securities so long as the stabilizing bids do not exceed a specified maximum.

Syndicate covering transactions involve purchases of the offered securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the representative of the underwriters to reclaim a selling concession from a syndicate member when the offered securities originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Such stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the offered securities to be higher than it would otherwise be in the absence of such transactions. These transactions may be effected on a national securities exchange and, if commenced, may be discontinued at any time. Underwriters, dealers and agents may be customers of, engage in transactions with or perform services for, us and our subsidiaries in the ordinary course of business.

We will bear all costs, expenses and fees in connection with the registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of any of our securities by us.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION OF DOCUMENTS BY REFERENCE

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

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

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

1. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2009, filed on May 15, 2009;
2. Our Amendment to our Annual Report on Form 10-K/A for the year ended December 31, 2008, filed on April 29, 2009;
3. Our Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 30, 2009;
4. Our Current Reports on Form 8-K filed with the Commission on January 28, 2009, January 30, 2009, March 25, 2009, May 1, 2009 and May 7, 2009;
5. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the Commission on November 19, 1997, and May 10, 2004; and
6. All documents we have filed with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

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

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

LEGAL MATTERS

Legal matters with respect to the securities offered hereby are being passed upon for us by Morgan, Lewis and Bockius, LLP, Princeton, New Jersey.

EXPERTS

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

$10,500,000
DEBT SECURITIES
WARRANTS
PREFERRED STOCK
COMMON STOCK

PROSPECTUS

May , 2009

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an itemization of the various expenses, all of which we will pay, in connection with the issuance and distribution of the securities being registered. All of the amounts shown are estimated except the SEC Registration Fee.

SEC Registration Fee	$	590
Printing and Engraving Fees		15,000
Legal Fees and Expenses		15,000
Accounting Fees and Expenses		20,000
Transfer Agent and Registrar Fees		10,000
Trustee s Fees and Expenses		10,000
Miscellaneous		9,410
Total	$	80,000

Item 15. Indemnification of Directors and Officers

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

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

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

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

Item 16. Exhibits

The exhibits to this Registration Statement are listed in the Exhibit Index to this Registration Statement, which Exhibit Index is hereby incorporated by reference.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in

the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, *however*, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by these paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this Registration Statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the Registration Statement.

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

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

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

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

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

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

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

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

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

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

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

(e) If and when applicable, the undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Flemington, State of New Jersey on May 26, 2009.

NOVADEL PHARMA INC.

By: /s/ STEVEN B. RATOFF

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

POWER OF ATTORNEY

We, the undersigned officers and directors of NovaDel Pharma Inc., hereby constitute and appoint Steven B. Ratoff, our true and lawful attorney, with full power to sign for us and in our names in the capacities indicated below, the registration statement on Form S-3 filed herewith and any and all subsequent amendments to said registration statement, and generally to do all such things in our names and on our behalf in our capacities as officers and directors to enable NovaDel Pharma Inc. to comply with the provisions of the Securities Act, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to said registration statement and any and all amendments thereto.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURES	TITLE	DATE
/S/ STEVEN B. RATOFF Steven B. Ratoff	Chairman, Interim President and Chief Executive Officer, Interim Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)	May 26, 2009
/S/ MARK J. BARIC Mark J. Baric	Director	May 26, 2009
/S/ THOMAS E. BONNEY Thomas E. Bonney	Director	May 26, 2009
/S/ WILLIAM F. HAMILTON William F. Hamilton, Ph.D.	Director	May 26, 2009
/S/ J. JAY LOBELL J. Jay Lobell	Director	May 26, 2009
/S/ CHARLES NEMEROFF Charles Nemeroff	Director	May 26, 2009

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement *
4.1	Form of Senior Indenture ***
4.2	Form of Subordinated Indenture ***
4.3	Certificate of Designations of Preferred Stock *
4.4	Form of Preferred Stock Certificate *
4.5	Form of Warrant *
5.1	Opinion of Morgan, Lewis & Bockius, LLP **
12.1	Statement of Computation of Ratios of Earnings to Fixed Charges **
23.1	Consent of J.H. Cohn LLP, Independent Auditors **
23.2	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1) **
24.1	Powers of Attorney (included on signature page to this Registration Statement) **
25.1	Form T-1 Statement of Eligibility of Law Debenture Trust Company of New York, as trustee under the Senior Indenture ***
25.2	Form T-1 Statement of Eligibility of Law Debenture Trust Company of New York, as trustee under the Subordinated Indenture ***

* To be filed, if necessary, by amendment as an exhibit to a report pursuant to Sections 13(a), 13(c) or 15(d) of the Exchange Act or subsequent Current Report on Form 8-K.

** Filed herewith

*** To be filed by pre-effective amendment.