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.

TABLE OF CONTENTS

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 anti