NOVADEL PHARMA INC
Form 10-K
March 30, 2009

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-K

**[ X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the year ended December 31, 2008

OR

**oTRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES**

**EXCHANGE ACT OF 1934**

*COMMISSION FILE NO. 001-32177*

# NOVADEL PHARMA INC.

(Exact Name of registrant as specified in its charter)

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

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant's telephone number, including area code

**Securities registered pursuant to Section 12(b) of the Exchange Act:**

| **Title of each class** | **Name of each exchange on which registered** |
|---|---|
| **Common Stock, par value $0.001 per share** | **NYSE Amex LLC** |

**Securities registered pursuant to Section 12(g) of**

**the Exchange Act:**

**None**

Indicate by check mark if the registrant is a well-know seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 definition of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of June 30, 2008, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $12 million based upon the closing sale price of $0.23 for the Registrant's common stock, $0.001 par value, as reported by the NYSE Amex LLC, formerly known as the American Stock Exchange on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2009, the issuer had 61,061,374 shares of common stock, $0.001 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement to be filed pursuant to Regulation 14A within 120 days of the end of the fiscal year (December 31, 2008) are incorporated by reference into Part III of this Annual Report on Form 10-K.

**NOVADEL PHARMA INC.**

**ANNUAL REPORT ON FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2008**

**TABLE OF CONTENTS**

Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include NovaDel Pharma Inc. (NovaDel).

**SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

This Annual Report on Form 10-K includes “forward-looking statements”, including statements regarding NovaDel Pharma Inc.’s (the “Company,” “we,” “us” or “NovaDel”) expectations, beliefs, intentions or strategies for the future and the Company’s internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company’s views as of the date they are made with respect to future events and financial performance. In particular, the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in Part II, Item 7 of this Annual Report includes forward-looking statements that reflect the Company’s current views with respect to future events and financial performance. The Company uses words such as “expect,” “anticipate,” “believe,” “intend” and similar expressions to identify forward-looking statements. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. A number of important risks and uncertainties could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company’s financial condition; the progress of the Company’s research and development; clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in the Company’s clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company’s ability to obtain additional required financing to fund its research programs; the Company’s ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the U.S. Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company’s clinical trials and the marketing of the Company’s products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company’s internal controls and procedures; and the risks identified under the section entitled “Risk Factors” included as Item 1A in Part I of this Annual Report on Form 10-K and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

**PART I**

**ITEM 1. BUSINESS.**

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

of December 31, 2007, representing a net decrease in working capital of approximately $3,764,000.

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

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 throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

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

On May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) 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 December 31, 2008, 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 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.

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.

7

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

Highlights for the year ended December 31, 2008, and additionally through the date of filing of this Annual Report on Form 10-K, include the following product development and business achievements:

*Product Pipeline*

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

- Announced the results of a clinical study comparing our tizanidine oral spray with tizanidine tablets, where our oral spray met primary pharmacokinetic and pharmacodynamic and safety objectives.

- Announced the results of a pilot efficacy study comparing our NVD-201 with Imitrex® tablets, where our oral spray was safe and effective in relieving migraine headaches at a lower dosage than that for the Imitrex® tablets.

- Announced that the U.S. Food and Drug Administration had requested an extension of up to three months on our New Drug Application for Zolpimist™ in order to complete their review.

- Updated our website and corporate presentation for our new product pipeline, as discussed further below.

- Announced that Par Pharmaceuticals had recently completed bioequivalence studies on Zensana™ with mixed results, and that Par would be working with us to carefully review and understand the results of the studies before determining the next steps for Zensana™.

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

*Intellectual Property*

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

*Other*

- Announced that we had entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P. for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock, 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 had closed the initial portion of the 2008 Financing, referred to herein as the Initial Closing, for an aggregate gross proceeds of $1,475,000, in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

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

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

**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*** | | | | |
| | | Nausea/Vomiting | Clinical development | Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A. |

| | | | | |
|---|---|---|---|---|
| Zensana™ | ondansetron | | | |
| 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, in November 2008, Par announced that it had completed bioequivalency studies on Zensana™ with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies to determine the work necessary to complete Zensana™'s development and proceed with an NDA submission.

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

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

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

11

**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 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 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 (See Note 9).

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 (See Note 9). 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 twelve months ended December 31, 2008, we recognized $96,000 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. Ourproprietary 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, 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 are in the process of transferring 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 $351,000 during the year ended December 31, 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.

24

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.

25

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 March 20, 2009, we had 10 total employees, all of whom were full-time employees.

The names and ages of our Directors and Executive Officers as of the date of filing this Annual Report on Form 10-K are set out below. All Directors are elected annually, to serve until the next annual meeting of stockholders and until their successors are duly elected and qualified. Executive Officers are elected annually by the Board of Directors and serve at the Board of Directors' pleasure. The Board of Directors has determined that the following individuals are the Executive Officers of the Company: Mr. Ratoff, Dr. Bergstrom, Mr. Spicer and Dr. Zodda.

| NAME | AGE | POSITION WITH THE COMPANY |
|---|---|---|
| Mark J. Baric | 50 | Director |
| Thomas E. Bonney | 44 | Director |
| William F. Hamilton, Ph.D. | 69 | Director |
| J. Jay Lobell | 46 | Director |
| Charles Nemeroff, M.D., Ph.D. | 59 | Director |
| Steven B. Ratoff | 66 | Chairman of the Board of Directors, Interim President and Chief Executive Officer |
| David H. Bergstrom, Ph.D. | 54 | Senior Vice President and Chief Operating Officer |
| Michael E. Spicer(1) | 55 | Chief Financial Officer and Corporate Secretary |
| Deni M. Zodda, Ph.D.(1) | 55 | Senior Vice President and Chief Business Officer |

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(1) On March 19, 2009, Michael E. Spicer notified our Board of Directors of his intention to resign as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. There is no disagreement between us and Mr. Spicer concerning our policies, procedures and operations. Effective April 1, 2009, Deni Zodda shall serve as Interim Chief Financial Officer and Corporate Secretary and Joseph W. Warusz, a consultant, shall serve as our principal accounting officer.

***Mark J. Baric***, Director, 50. Mr. Baric was elected to the Board in February 2007. Since 2005, Mr. Baric has been the President and co-founder of CeNeRx BioPharma, Inc., a privately-held development company with a therapeutic focus on diseases of the central nervous system. In 2001 he co-founded and served, until 2005, as Chief Executive Officer and Chairman of 2ThumbZ Entertainment Inc., a privately-held company which develops and markets entertainment applications for users of handheld wireless devices and networks. From 1996 to 2001, Mr. Baric was Chairman and Chief Executive Officer of Virtus Entertainment Corporation, an emerging company in the fast-growing interactive entertainment industry. From 1990 to 1996, Mr. Baric held various leadership positions, including Chief Operating Officer and Chief Financial and Administrative Officer of Seer Technologies Inc. (now known as Cicero, Inc.), a provider of business integration software. Prior to 1990, Mr. Baric held various leadership positions at several firms, including CS First Boston and Coopers and Lybrand. Mr. Baric serves on the boards of CeNeRx BioPharma, Inc. and 2ThumbZ Entertainment Inc. Mr. Baric received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. from Clarion University. He is a member of our Audit Committee and a member of our Compensation Committee.

***Thomas E. Bonney***, CPA, Director, 44. Mr. Bonney was elected to the Board in March 2005. From 2002 to the present, Mr. Bonney has been Managing Director of CMF Associates, LLC, a financial and management consulting firm. Since December 2006, Mr. Bonney has been a General Partner in West Place LLC, and West Place Restaurant Group, LLC, privately-held companies that invest in and manage hotels and real estate. Since June 2005, Mr. Bonney has been a Director of Leblon Holdings LLC, a privately-held beverage supplier and from June 2005 through July 2007 was the Chief Financial Officer of Leblon Holdings, LLC. From 2001 to 2002, he was Chief Financial Officer of Akcelerant

Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touche from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is a member and chair of our Audit Committee and a member of our Corporate Governance and Nominating Committee.

***William F. Hamilton***, Ph.D., Director, 69. Dr. Hamilton was elected to the Board in March 2003. In January 2006, Dr. Hamilton was appointed Lead Independent Director. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. He serves as a director of Neose Technologies, Inc., a publicly-traded company developing proprietary drugs; Arno Therapeutics, Inc., a publicly-traded biopharmaceutical company focused on the development of innovative products for the treatment of cancer patients; Yaupon Therapeutics, Inc., a privately-held specialty pharmaceutical company that develops small molecule pharmaceuticals licensed from under-served academic laboratories; Avid Radiopharmaceuticals, Inc., a privately-held clinical-stage product-focused molecular imaging company and Neuro Diagnostic Devices, a privately-held development-stage medical device company. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of our Audit Committee and a member and chair of our Corporate Governance and Nominating Committee.

***J. Jay Lobell***, Director, 46. Mr. Lobell was elected to the Board in December 2005. Mr. Lobell has served as President and Chief Operating Officer of Paramount BioCapital Asset Management, Inc. and Paramount Biosciences, LLC since January 2005, and is a registered representative of Paramount BioCapital, Inc. From 1996 until January 2005, Mr. Lobell was a partner at Covington & Burling, a law firm. Mr. Lobell received his B.A. from Queens College and his J.D. from Yale Law School. Mr. Lobell is a director of Chem Rx Corporation, a publicly-traded long-term care pharmacy, as well as several private biotechnology companies. Mr. Lobell is a member and chair of our Compensation Committee.

***Charles Nemeroff***, M.D., Ph.D., Director, 59. Dr. Nemeroff was elected to the Board in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor in the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia, since 1991. Dr. Nemeroff has served on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals, Forest Laboratories, Janssen and Quintiles. In 2002, he was elected to the Institute of Medicine of the National Academy of Sciences. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University, his Ph.D. and post doctorate training from the University of North Carolina and his M.D. from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory Board. He is also a member of our Compensation Committee and is a member of our Corporate Governance and Nominating Committee.

***Steven B. Ratoff***, Chairman of the Board, Interim President and Chief Executive Officer, 66. Mr. Ratoff was elected to the Board in January 2006 and was elected Chairman of the Board on September 15, 2006. He was appointed as Interim President and Chief Executive Officer of NovaDel on July 23, 2007. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest Investments, a health care venture capital firm. Mr. Ratoff has been a director, since May 2005, and was Chairman of the Board, from September 2005 to October 2006, of Torrey Pines Therapeutics Inc. (formerly Axonyx Inc.), a NASDAQ development stage pharmaceutical company. Mr. Ratoff served as a director of Inkine Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December, 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a publicly-traded diversified manufacturer of consumer products. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

***David H. Bergstrom***, Ph.D., Senior Vice President and Chief Operating Officer, 54.Dr. Bergstrom joined NovaDel in December 2006 as Senior Vice President and Chief Operating Officer.From 1999 to November 2006, Dr. Bergstrom served in several capacities at Cardinal Health, Inc., including Vice President, Research & Development and Senior Vice President and General Manager. From 1998 to 1999, Dr. Bergstrom was Vice President of Pharmaceutical & Chemical Development at Guilford Pharmaceuticals Inc. Dr. Bergstrom was employed by Hoechst Marion Roussel, Inc. as the Director of Pharmaceutical and Analytical Sciences from 1996 to 1998. Dr. Bergstrom served as Director of Pharmaceutical and Analytical Development for the predecessor company, Hoechst-Roussel Pharmaceuticals Inc., from 1991 to 1996, and Group Manager, Formulations, Pharmaceutical Research from 1990 to 1991. Prior thereto, Dr. Bergstrom held various positions at Ciba-Geigy Corporation. Dr. Bergstrom received his Ph.D. in Pharmaceutics at the University of Utah in 1985. In addition, he received his M.S. in Pharmaceutical Chemistry at the University of Michigan in 1982 and his B.S. degree in Pharmacy in 1978 at Ferris State University.

***Michael E. Spicer***, CPA, Chief Financial Officer and Corporate Secretary, 55. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004 and was named Corporate Secretary in April 2006. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.). From September 1998 to December 2001, Mr. Spicer served as Vice President, Chief Financial Officer of Lifecodes Corporation until it was acquired by Orchid. Mr. Spicer is a Certified Public Accountant and holds an undergraduate degree in Accounting from the University of Virginia and an M.B.A. from Harvard Business School. On March 25, 2009, Mr. Spicer announced his intention to resign as Chief Financial Officer and Corporate Secretary effective April 1, 2009.

***Deni M. Zodda***, Ph.D., Senior Vice President and Chief Business Officer, 55. Dr. Zodda joined NovaDel in February 2007 as Senior Vice President and Chief Business Officer. From May 2006 to February 2007, Dr. Zodda was Principal of Medignostica, LLC, a consulting firm he owns which provided business development services to various clients and was acting Chief Executive Officer of StemCapture, Inc., a privately-held stem cell research company. From 2000 to May 2006, Dr. Zodda served in varying capacities, including Senior Vice President, Business Development and Principal Financial Officer of Discovery Laboratories, Inc. From 1998 to 2000, Dr. Zodda served as Managing Director of the Life Sciences Practice at KPMG. During the course of his career, Dr. Zodda also held senior management positions in business development, marketing and commercial operations at Cephalon, Inc., Wyeth, Baxter International Inc. and SmithKline Beckman, Inc. Dr. Zodda received his M.B.A. in Marketing and Finance from the University of Santa Clara in 1986, his Ph.D. in Biology from the University of Notre Dame in 1980 and his B.S. in Biology from Villanova University in 1975. On March 25, 2009, our Board of Directors appointed Dr. Zodda to serve as Interim Chief Financial Officer, Principal Financial Officer and Corporate Secretary, beginning April 1, 2009.

**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 dzodda@novadel.com or contact Deni Zodda, our Interim Chief Financial Officer, beginning April 1, 2009, at 25 Minneakoning Road, Flemington, New Jersey, 08822 or at 908-782-3431, ext. 2424.

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 Annual Report on Form 10-K.

**ITEM 1A. 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 the Company.

**WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.**

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

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing throughout 2008, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products, we believe that we will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We received $1,475,000 in gross proceeds on May 30, 2008 from the initial closing of a convertible note financing with certain funds affiliated with ProQuest Investments, referred to herein as the Initial Closing, and received $2,525,000 in gross proceeds on October 17, 2008 from the subsequent closing of such convertible note financing, referred to herein as the Subsequent Closing. 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 and continued 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.

33

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

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

We are seeking to raise additional capital in early 2009 to fund our operations and future development activities through a license agreement or by taking advantage of other strategic opportunities. These opportunities could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. Our ability to fund operations is also dependent on whether ProQuest Investments, or ProQuest, to which we have issued $4.0 million of secured convertible notes in fiscal 2008, consisting of $1.5 million of notes issued in the initial closing on May 30, 2008, the Initial Closing Notes, and $2.5 million of notes issued in the subsequent closing on October 17, 2008, the Subsequent Closing Notes, demands payment under such notes. Given our current level of spending, if ProQuest demands payment under the Initial Closing Notes and the Subsequent Closing Notes, we will not be able to repay the notes in full, unless we are successful prior to that time in securing funds through new strategic partnerships and/or the sale of common stock or other securities. However, if ProQuest only demands payment under the Initial Closing Notes, fully converts the Subsequent Closing Notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through May 2009. If ProQuest only demands payment under the Subsequent Closing Noters, fully converts the Initial Closing Notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through April 2009. Lastly, if ProQuest chooses not to demand payment on the Initial Closing Notes and the Subsequent Closing Notes, and instead fully converts them into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through the early third quarter 2009. Subsequent to December 2008, and as of the date of this annual report on Form 10-K, although ProQuest did not convert its notes into common stock, ProQuest has not yet demanded payment under the notes.

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

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. However, if ProQuest only demands payment under the Initial Closing Notes, fully converts the Subsequent Closing Notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through May 2009. If ProQuest only demands payment under the Subsequent Closing Notes, fully converts the Initial Closing Notes into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through April 2009. Lastly, if ProQuest chooses not to demand payment on the Initial Closing Notes and the Subsequent Closing Notes, and instead fully converts them into shares of our common stock, and we are not successful in securing new funds, we will have sufficient cash on hand to fund operations through the early third quarter 2009. Subsequent to December 2008, and as of the date of this Annual Report on Form 10-K, although ProQuest did not convert its notes into common stock, ProQuest has not yet demanded payment under the notes.

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

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 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).

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

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

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

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

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

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

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

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

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

**THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.**

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

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

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

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

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

38

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

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

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

**WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.**

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of the calendar year 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for Zolpimist™, our zolpidem oral spray, was accepted by the FDA. On September 18, 2008, we announced that the FDA had requested an extension of up to three months on our NDA filing for Zolpimist™ in order to complete their review. On December 22, 2008, we announced that we had received approval from the FDA for our NDA for Zolpimist™ for the short-term treatment of insomnia. We are currently investigating strategic partners for both NitroMist™ and Zolpimist™. Our partner for Zensana™, Par Pharmaceuticals, recently announced that it had completed bioequivalency studies on Zensana with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We are working with Par to carefully review and better understand the results from these studies before determining the next steps for Zensana™. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us. Since the fourth quarter 2007, 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 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).

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.

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damages note).

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

**WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.**

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

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

**WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.**

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

**WE ARE DEPENDENT ON OUR SUPPLIERS.**

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

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

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

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

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

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

**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 LLC, or NYSE Amex LLC 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.

45

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 and the continued listing of our common stock on the NYSE Amex LLC 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 LLC providing notification that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex LLC 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 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. We submitted a plan to the NYSE Amex LLC 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 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 September 30, 2008, 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 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.

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

49

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

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

**WE ARE INFLUENCED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.**

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of March 20, 2008, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 40.3% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest Investments has the ability to exert significant influence over matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

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

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

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks set forth in these Risk Factors and other reports, including this prospectus and other filings filed with the Securities and Exchange Commission from time to time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

52

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 Annual Report on Form 10-K, such shelf registration statement is no longer effective.

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

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

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

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

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

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

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

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

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

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

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

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

**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 partial 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).

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

Our executive offices, laboratory, and warehousing space are located at 25 Minneakoning Road, Flemington, New Jersey, known as the Facility. The Facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease, expiring in August 2013. Presently, we are only occupying a portion of our space in the Facility. During the five months ended December 31, 2006, we paid rent for the Facility of approximately $184,000. During the years ended December 31, 2007 and 2008, we paid rent for the Facility of approximately $443,000 and $453,000, respectively. The 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 have contracted out manufacturing for our product candidates. The manufacture of our product candidates is subject to cGMP prescribed by the Food & Drug Administration, or FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, “Business-Raw Materials and Suppliers” and Business-Government Regulations.”

**ITEM 3. LEGAL PROCEEDINGS.**

We are not a named party in any material legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

None

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock is traded on the NYSE Amex LLC under the ticker symbol "NVD" since May 11, 2004. The following table sets forth the range of high and low closing sales prices of our common stock as reported by the NYSE Amex LLC during the year ended December 31, 2007 and December 31, 2008.

| | CLOSING SALE PRICES | |
|---|---|---|
| | ($) | |
| YEAR ENDED DECEMBER 31, 2007 | | |
| First Quarter (January 1, 2007 through March 31, 2007) | 1.81 | 1.30 |
| Second Quarter (April 1, 2007 through June 30, 2007) | 1.33 | 1.02 |
| Third Quarter (July 1, 2007 through September 30, 2007) | 1.11 | 0.50 |
| Fourth Quarter (October 1, 2007 through December 31, 2007) | 0.54 | 0.21 |
| | HIGH | LOW |
| YEAR ENDED DECEMBER 31, 2008 | | |
| First Quarter (January 1, 2008 through March 31, 2008) | 0.51 | 0.28 |
| Second Quarter (April 1, 2008 through June 30, 2008) | 0.35 | 0.22 |
| Third Quarter (July 1, 2008 through September 30, 2008) | 0.30 | 0.17 |
| Fourth Quarter (October 1, 2008 through December 31, 2008) | 0.46 | 0.06 |

The last closing sales price of our common stock as reported on the NYSE Amex LLC on March 20, 2009 was $0.29. As of March 20, 2009, there were approximately 81 record holders of our common stock.

We have never declared or paid a dividend on our common stock and management expects that all or a substantial portion of our future earnings will be retained for expansion or development of our business. The decision to pay dividends, if any, in the future is within the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management does not anticipate that we will pay dividends on our common stock in the foreseeable future. Moreover, we may never issue dividends in the future.

**EQUITY COMPENSATION PLANS**

The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2008.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans |
|---|---|---|---|
| Equity compensation plans approved by security holders | 4,737,000 | $ 1.48 | 3,258,000 |
| Equity compensation plans not approved by security holders | 730,000 | 2.29 | — |
| Total | 5,467,000 | $ 1.59 | 3,258,000 |

**PERFORMANCE GRAPH**

The graph below compares changes in the cumulative total stockholder return (change in stock price plus reinvested dividends) for the period from July 31, 2003 through December 31, 2008 of an initial investment of $100 invested in (a) NovaDel Pharma Inc.'s common stock, (b) the Total Return Index for the AMEX Composite and (c) the Research Data Group (RDG) Microcap Pharmaceutical Index. Total Return Index values are prepared by the Research Data Group. The stock price performance is not included to forecast or indicate future price performance.

| | 7/03 | 7/04 | 7/05 | 7/06 | 12/06 | 12/07 | 12/08 |
|---|---|---|---|---|---|---|---|
| **NovaDel Pharma Inc.** | $ 100.00 | $ 84.24 | $ 61.58 | $ 59.11 | $ 80.79 | $ 11.82 | $ 15.76 |
| **AMEX Composite** | $ 100.00 | $ 132.24 | $ 178.97 | $ 218.20 | $ 234.07 | $ 276.26 | $ 168.56 |
| **RDG MicroCap Pharmaceutical** | $ 100.00 | $ 86.07 | $ 83.89 | $ 69.52 | $ 72.65 | $ 55.08 | $ 23.47 |

**ITEM 6. SELECTED FINANCIAL DATA.**

The following Selected Financial Data should be read in conjunction with our Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report on Form 10-K. The data set forth below with respect to our Statements of Operations 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, and the Balance Sheet data as of December 31, 2008 and 2007 are derived from our Financial Statements which are included elsewhere in this Annual Report on Form 10-K and are qualified by reference to such Financial Statements and related Notes thereto. The data set forth below for the year ended December 31, 2006 and for the five months ended December 31, 2005, are unaudited. In Management's Discussion and Analysis of Financial Condition and Results of Operations, the year ended December 31, 2007 is compared to 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. The data set forth below with respect to our Statements of Operations for the fiscal years ended July 31, 2005 and 2004 and the Balance Sheet data as of July 31, 2006, July 31, 2005, and July 31, 2004 are derived from our Financial Statements, which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

| | Years Ended December 31, | | | Five Months Ended December 31, | | Years Ended July 31, | | |
|---|---|---|---|---|---|---|---|---|
| **Statement of Operations Data:** | **2008** | **2007** | **2006** | **2006** | **2005** | **2006** | **2005** | **2004** |
| | | | **(unaudited)** | | **(unaudited)** | | | |
| Total Revenues | $ 361,000 | $ 469,000 | $ 3,280,000 | $ 2,067,000 | $ 677,000 | $ 1,890,000 | $ 439,000 | $ 466,000 |
| Total Expenses | 8,951,000 | 18,656,000 | 13,544,000 | 6,519,000 | 5,429,000 | 12,454,000 | 10,217,000 | 7,119,000 |
| Loss from Operations | (8,590,000) | (18,187,000) | (10,264,000) | (4,452,000) | (4,752,000) | (10,564,000) | (9,778,000) | (6,653,000) |
| Other, net | — | (66,000) | — | — | — | — | — | — |
| Interest Expense | 1,868,000 | — | — | — | — | — | — | — |
| Interest Income | 137,000 | 632,000 | 337,000 | 180,000 | 67,000 | 224,000 | 87,000 | 98,000 |
| Income Tax Benefit | (735,000) | (658,000) | (467,000) | (467,000) | (256,000) | (256,000) | (241,000) | (214,000) |
| Net Loss | $ (9,586,000) | $ (16,963,000) | $ (9,460,000) | (3,805,000) | $ (4,429,000) | $ (10,084,000) | $ (9,450,000) | $ (6,341,000) |
| Basic and Diluted Loss Per Common Share | $ (0.16) | $ (0.29) | $ (0.20) | $ (0.08) | $ (0.11) | $ (0.23) | $ (0.27) | $ (0.24) |
| Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share | 59,592,000 | 59,497,000 | 46,732,000 | 49,522,000 | 40,619,000 | 43,000,000 | 34,808,000 | 26,269,000 |

| | December 31, | | | July 31, | | |
|---|---|---|---|---|---|---|
| **BALANCE SHEET DATA:** | **2008** | **2007** | **2006** | **2006** | **2005** | **2004** |
| Cash, cash equivalents, and short-term investments | $ 4,328,000 | $ 6,384,000 | $ 20,276,000 | $ 10,138,000 | $ 8,223,000 | $ 8,377,000 |
| Total Assets | 7,316,000 | 10,363,000 | 24,316,000 | 14,822,000 | 13,028,000 | 11,486,000 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Total Current Liabilities | 5,563,000 | 4,211,000 | 3,146,000 | 2,200,000 | 2,405,000 | 1,086,000 |
| Total Liabilities | 10,057,000 | 6,189,000 | 5,718,000 | 4,777,000 | 5,079,000 | 1,463,000 |
| Accumulated deficit | (74,829,000) | (65,243,000) | (48,280,000) | (44,475,000) | (34,391,000) | (24,941,000) |
| Total Stockholders' Equity (Deficit) | $ (2,741,000) | $ 4,174,000 | $ 18,598,000 | $ 10,045,000 | $ 7,949,000 | $ 10,023,000 |

60

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following discussion of our financial condition and result of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Item 1A. "Risk Factors" of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward looking statements.

**GENERAL**

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed drugs. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have eight patents which have been issued in the U.S. and 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.

We have had a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2008 of $74,829,000, as compared to $65,243,000 as of December 31, 2007. We have had negative cash flow from operating activities of $5,533,000 and $15,240,000 for the years ended December 31, 2008 and 2007, respectively. As of December 31, 2008, we had working capital of $47,000, as compared to $3,811,000 as of December 31, 2007, representing a net decrease in working capital of approximately $3,764,000.

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

61

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

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

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

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

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

62

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

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

In addition, as of December 31, 2008, 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.

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

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

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

Highlights for the year ended December 31, 2008, and additionally through the date of filing of this Annual Report on Form 10-K, 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 had closed the initial portion of the 2008 Financing, referred to herein as the Initial Closing, for an aggregate gross proceeds of $1,475,000, in the form of secured convertible promissory notes and warrants to purchase shares of our common stock.

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

§ Announced that Michael E. Spicer intends to resign as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. Our Board of Directors appointed Deni M. Zodda, our Chief Business Officer, to serve as 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.

64

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. 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. 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 other 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.

68

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.

69

**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.

**CRITICAL ACCOUNTING POLICIES**

USE OF ESTIMATES - The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

CASH AND CASH EQUIVALENTS – Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. We maintain our cash and cash equivalents with several financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed on demand and are maintained with high quality financial institutions, therefore reducing credit risk.

REVENUE RECOGNITION – We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

DEFERRED FINANCING COSTS – We capitalize the costs related to the issuance of our convertible notes, and amortize such deferred costs to interest expense on a straight-line basis over the life of the related notes. We capitalized approximately $238,000 of deferred financing costs associated with the issuance of our convertible notes during the year ended December 31, 2008, and amortized approximately $213,000 to expense during the year ended December 31, 2008.

WARRANTS ISSUED WITH CONVERTIBLE NOTES – We account for the value of warrants and the intrinsic value of beneficial conversion rights arising from the issuance of convertible notes pursuant to the consensuses for EITF Issue No. 98-5, EITF Issue No. 00-19 and EITF Issue No. 00-27. Such values are determined by allocating an appropriate portion of the proceeds received from the debt instruments to the debt and warrants based on their relative fair value, which was determined using the Black-Scholes model.

VALUATION OF LONG-LIVED ASSETS – We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Our long-lived assets as of December 31, 2008 were represented by property and equipment, as we have no intangible assets on our balance sheet. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management's best estimate using appropriate assumptions and projections at that time. Net long-lived property and equipment as of December 31, 2008 was $1.4 million. We reviewed our long-lived property and equipment as of December 31, 2008, and have determined that their estimated fair value exceeds the carrying amount of such assets; therefore, we have not recognized an impairment loss for our long-lived property and equipment.

STOCK-BASED COMPENSATION – In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," SFAS 123R, which revises "Accounting for Stock-Based Compensation," SFAS 123 and superseded Accounting Principles Board APB Opinion No. 25, "Accounting for Stock Issued to Employees," APB 25, which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R required all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

We have adopted the provisions of SFAS 123, and have selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Using the fair value method required by SFAS 123R, we recorded share-based compensation expense of $771,000, or $0.01 per share, for the year ended December 31, 2008, $910,000, or $0.02 per share, for the year ended December 31, 2007, and $1,179,000, or $0.03 per share, for the year ended December 31, 2006. For the five months ended December 31, 2006 and 2005, we recorded share-based compensation of approximately $498,000 or $0.01 per share and $520,000 or $0.01 per share, respectively. For the fiscal year ended July 31, 2006, we recorded share-based compensation expense of approximately $1.2 million or $0.03 per share. Share-based compensation for the year ended December 31, 2007 included a $0.5 million credit relating to the modification and accelerated vesting of stock options issued to our former President and CEO, Dr. Jan Egberts. We will continue to incur share-based compensation charges in future periods. As of December 31, 2008, unamortized stock-based compensation expense of $1.5 million remains to be recognized, which is comprised of $391,000 related to non-performance based stock options to be recognized over a weighted average period of 1.4 years, $382,000 related to restricted stock to be recognized over a weighted average period of 1.9 years, and $727,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when we determine that it is probable that the milestone will be reached.

RESEARCH AND DEVELOPMENT EXPENSES - Research and development costs are expensed as incurred.

**RESULTS OF OPERATIONS**

**YEARS ENDED DECEMBER 31, 2008 AND DECEMBER 31, 2007**

License fees and milestone fees earned for the year ended December 31, 2008 were $361,000, as compared to $469,000 for the year ended December 31, 2007. The decrease is primarily due to a non-recurring milestone payment received in the year ended December 31, 2007 from our license agreement with Velcera for veterinary products, which more than offset a one-time payment received during 2008 in connection with a product candidate that had been in development several years ago, and was no longer in our active product candidate pipeline.

Research and development expenses for the year ended December 31, 2008 were $3,878,000 as compared to $11,940,000 for the year ended December 31, 2007. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the years ended December 31, 2008 and 2007:

| | **Fiscal Year Ended December 31, 2008** | **December 31, 2007** |
|---|---|---|
| NitroMist™ | $135,000 | $558,000 |
| Zolpimist™ | 893,000 | 5,669,000 |
| Sumatriptan | 369,000 | 813,000 |
| Zensana™ | 37,000 | 213,000 |
| Tizanidine | 41,000 | 75,000 |
| Ropinirole | — | 3,000 |
| Other research and development costs | 242,000 | 1,763,000 |
| Internal costs | 2,161,000 | 2,846,000 |
| Total research and development expenses | $3,878,000 | $11,940,000 |

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpimist™, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. 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 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;

- Zensana™ - third-party direct project expenses relating to the development of Zensana™. As our partner for the Zensana™, Par, is overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to this product candidate. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana™, as described above, we devoted resources to this project during the year ended December 31, 2007, including approximately $204,000 in third-party costs;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the year ended December 31, 2008 decreased primarily as a result of the following items:

- $4,776,000 decrease in product development costs for our Zolpimist™ product candidate, as development efforts were substantially completed during the fourth quarter 2007, including filing of an NDA. Development costs for zolpidem in the first quarter 2007 included costs for clinical trials, manufacturing preparedness and other NDA preparatory costs;

- $176,000 decrease in product development costs related to Zensana™, as noted above;

- $423,000 decrease in costs associated with our NitroMist™ product candidate primarily due to process validation and method transfer activities in the year ended December 31, 2007, which were substantially lower in the year ended December 31, 2008;

- $444,000 decrease in product development costs for our Sumatriptan product candidate, as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007; and

- $1,521,000 decrease in other research and development costs as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007.

Consulting, selling, general and administrative expenses for the year ended December 31, 2008 were $4,722,000 as compared to $6,716,000 for the year ended December 31, 2007. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to reduced salaries, benefits and other employee-related expenses, and to lower stock compensation charges.

The loss on disposal of assets held for sale was $351,000 for the year ended December 31, 2008.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2008 were $8,951,000, as compared to $18,656,000 for the year ended December 31, 2007.

Other, net for the year ended December 31, 2007 was $66,000, as further detailed below in the comparison for the years ended December 31, 2007 and 2006. There was no Other, net for the year ended December 31, 2008.

Interest expense for the year ended December 31, 2008 was $1,868,000, of which $1,837,000 related to the convertible notes that were issued during 2008. This included $1,498,000 related to the amortization of the debt discount related to the beneficial conversion feature and fair value of the warrants, as well as $213,000 related to the amortization of the deferred financing costs.

Interest income for the year ended December 31, 2008 was $137,000 as compared to $632,000 for the year ended December 31, 2007 due to lower average cash and short-term investment balances.

The resulting net loss for the year ended December 31, 2008 was $9,586,000, as compared to $16,963,000 for the year ended December 31, 2007.

**YEARS ENDED DECEMBER 31, 2007 AND DECEMBER 31, 2006 (UNAUDITED)**

License fees and milestone fees earned from related parties for the year ended December 31, 2007 were $469,000, as compared to $3.2 million for the unaudited fiscal year ended December 31, 2006. The decrease is primarily due to non-recurring milestone payments received in connection with our license and development agreement with Hana Biosciences in the year ended December 31, 2006.

Consulting revenues from related parties for the year ended December 31, 2007 were $0, as compared to $118,000 for the year ended December 31, 2006. The decrease is due to lower revenue from Velcera for veterinary products. We are not currently performing any development work for Velcera.

Research and development expenses for the year ended December 31, 2007 were $11,940,000 as compared to $6,589,000 for the year ended December 31, 2006. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the years ended December 31, 2007 and December 31, 2006 (unaudited).

| | **Fiscal Year Ended December 31, 2007** | **December 31, 2006** |
|---|---|---|
| | | **(Unaudited)** |
| NitroMist™ | $558,000 | $1,331,000 |
| Zolpidem | 5,669,000 | 1,719,000 |
| Sumatriptan | 813,000 | 394,000 |
| Zensana™ | 213,000 | — |
| Propofol | — | — |
| Tizanidine | 75,000 | 161,000 |
| Ropinirole | 3,000 | 58,000 |
| Other research and development costs | 1,763,000 | 1,110,000 |
| Internal costs | 2,846,000 | 1,816,000 |
| Total research and development expenses | $11,940,000 | $6,589,000 |

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. During the fourth quarter 2007 and continuing throughout 2008, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured 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;

- Zensana™ and Propofol - third-party direct project expenses relating to the development of Zensana™ and our Propofol product candidate. As our partners for the Propofol product candidate, Manhattan Pharmaceuticals, and for Zensana™, Par, are overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to these product candidates. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana™, as described above, we devoted resources to this project during the three months ended March 31, 2007, including approximately $204,000 in third-party costs;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

74

Research and development expenses in the year ended December 31, 2007 increased primarily as a result of the following items:

- $3,950,000 increase primarily related to product development costs for our Zolpidem product candidate, including costs for clinical trials, manufacturing preparedness and other NDA preparatory costs;
- $419,000 increase primarily related to product development costs for our Sumatriptan product candidate, including costs for clinical trials and manufacturing preparedness;
- $1,031,000 increase in internal costs primarily due to an increase in payroll and other compensation costs as of result of research and development related higher headcount; and
- $773,000 decrease in costs associated with our NitroMist™ product candidate primarily due to process validation and method transfer activities in the year ended December 31, 2006, which did not recur in the year ended December 31, 2007.

General and administrative expenses for the year ended December 31, 2007 were $6,716,000 as compared to $6,955,000 for the year ended December 31, 2006. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The slight decrease in general and administrative expenses is primarily attributable to lower stock compensation charges and a greater proportion of payroll associated with research and development activities, partially offset by higher legal expenses.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2007 were $18,656,000, as compared to $13,544,000 for the year ended December 31, 2006.

Other, net for the year ended December 31, 2007 is comprised of the following items:

| | **December 31, 2007** |
|---|---|
| Other than temporary impairment of investment in marketable equity security | $ (360,000) |
| Loss from return of investment in marketable equity security to issuer | (140,000) |
| Write-off of deferred revenue relating to investment in marketable equity security | 434,000 |
| Total Other, net | $ (66,000) |

- $360,000 non-cash charge recorded to write-down our investment in Hana Biosciences as we determined that the decline in market value was other than temporary;

- $140,000 non-cash charge to account for the return of Hana Biosciences' shares, as a result of the Amended and Restated License Agreement with Hana Biosciences; and

- $434,000 benefit to write-off the remaining deferred revenue related to the shares received Hana Biosciences.

Interest income for the year ended December 31, 2007 was $632,000, as compared to $337,000 for the year ended December 31, 2006 due to higher average cash and short-term investment balances.

Income tax benefit for the year ended December 31, 2007 was $658,000, as compared to $467,000 for the year ended December 31, 2006. These increased income tax benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the year ended December 31, 2007 was $16,963,000, as compared to $9,460,000 for the year ended December 31, 2006.

**FIVE MONTHS ENDED DECEMBER 31, 2006 AND 2005 (UNAUDITED)**

License fees and milestone fees earned from related parties for the five months ended December 31, 2006 were $2,067,000, as compared to $568,000 for the unaudited five months ended December 31, 2005. The increase is primarily due to milestone payments received in connection with our license and development agreements for Zensana™ with Hana Biosciences and NitroMist™ with Par Pharmaceuticals.

Consulting revenues from related parties for the five months ended December 31, 2006 were $0 as compared to $109,000 for the five months ended December 31, 2005. The decrease is primarily attributable to lower levels of revenue from Velcera related to veterinary products.

Research and development expenses for the five months ended December 31, 2006 were $3,396,000, as compared to $2,082,000 for the five months ended December 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the five months ended December 31, 2006 and 2005.

| | **2006** | **2005** |
|---|---|---|
| | | **(Unaudited)** |
| NitroMist™ | $602,000 | $ 355,000 |
| Zolpidem | 1,216,000 | 380,000 |
| Sumatriptan | 109,000 | 118,000 |
| Zensana™ | — | 221,000 |
| Propofol | — | — |
| Alprazolam | — | — |
| Tizanidine | 161,000 | — |
| Ropinirole | 43,000 | — |
| Other research and development costs | 467,000 | 283,000 |
| Internal costs | 798,000 | 725,000 |
| Total research and development expenses | $3,396,000 | $ 2,082,000 |

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. We expect to devote the majority of our research and development resources to our zolpidem and sumatriptan product candidates and expect that costs associated with these product candidates should increase in future periods;

- Zensana™ and Propofol - third-party direct project expenses relating to the development of Zensana™. As our partners, Hana Biosciences and Manhattan Pharmaceuticals, are overseeing all clinical development and regulatory approval activities for these product candidates, we do not expect to devote a significant amount of resources to these product candidates;

- Alprazolam – third-party direct project expenses relating to the development of our alprazolam oral spray product candidate. We have determined that, in order to devote sufficient resources to other product candidates, it is appropriate to defer further efforts on alprazolam;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the five months ended December 31, 2006 increased primarily as a result of the following items:

- $247,000 increase related to the establishment of a reserve for certain raw materials and process validation batches for our NitroMist™ product candidate;
- $836,000 increase primarily related to product development and clinical trial costs for our zolpidem product candidate;
- $161,000 increase primarily related to product development costs for our tizanidine product candidate; and
- $221,000 decrease related to clinical trail material costs for Zensana™ incurred during the five months ended December 31, 2005. Such costs did not recur during the five months ended December 31, 2006.

Consulting, selling, general and administrative expenses for the five months ended December 31, 2006 were $3,123,000 as compared to $3,347,000 for the five months ended December 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in consulting, selling, general and administrative costs is primarily related to lower payroll and other personnel related costs during the period, partially offset by higher costs associated with external consultants.

Total costs and expenses for the five months ended December 31, 2006 were $6,519,000 as compared to $5,429,000 for the five months ended December 31, 2005 primarily due to the increase in research and development expenses, partially offset by the decrease in selling general and administrative expenses noted above.

Interest income for the five months ended December 31, 2006 was $180,000 as compared to $67,000 for the five months ended December 31, 2005 due to higher average cash and short-term investment balances and a general increase in interest rates.

Income tax benefit for the five months ended December 31, 2006 was $467,000 as compared to $256,000 for the five months ended December 31, 2005. These increased income tax benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the five months ended December 31, 2006 was $3,805,000 as compared to $4,429,000 for the five months ended December 31, 2005.

**LIQUIDITY AND CAPITAL RESOURCES**

From our inception, our principal sources of capital have been consulting revenues, private placements and public offerings of our securities, as well as loans and capital contributions from our principal stockholders. We have had a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2008 of $74,829,000, as compared to $65,243,000 as of December 31, 2007. We have had negative cash flow from operating activities of $5,533,000 and $15,240,000 for the years ended December 31, 2008 and 2007, respectively. As of December 31, 2008,

we had working capital of $47,000 as compared to $3,811,000 as of December 31, 2007, representing a net decrease in working capital of approximately $3,764,000. As explained further below, such decrease is primarily due to the loss for the year ended December 31, 2008 of $9,586,000.

Net cash used in operating activities was $5,533,000 for the year ended December 31, 2008, as compared to $15,240,000 for the year ended December 31, 2007. The $9,707,000 decrease in cash used is primarily due to the following:

- A reduction in net loss from $16,963,000 for the year ended December 31, 2007 to $9,586,000 for the year ended December 31, 2008, representing an improvement of $7,377,000.

- Non-cash expenses of $1,711,000 for the amortization of debt discount and deferred financing fees, and $370,000 for the loss on disposal of certain assets, during the year ended December 31, 2008.

- $2,756,000 increase in deferred revenue for the year ended December 31, 2008, as compared with a decrease of $628,000 for the year ended December 31, 2007. The significant increase in 2008 is due to the non-refundable license fee of $3,000,000 received from BioAlliance in May 2008.

- $151,000 decrease in prepaid expenses and other current assets for the year ended December 31, 2008, as compared with a $574,000 increase for the year ended December 31, 2007. The decrease in 2008 is due to the expiration of useful life on certain prepaid operating supplies at our contract manufacturer in Sweden, primarily due to the fact that we have significantly reduced our development activities since December 2007. The increase in 2007 was associated with our increasing investments during that year in our operating supplies at the same contract manufacturer in Sweden.

- These amounts were partially offset by a $2,322,000 decrease in accounts payable and accrued liabilities for the year ended December 31, 2008, as compared with an increase of $1,040,000 in the year ended December 31, 2007. The significant decrease in accounts payable and accrued liabilities in 2008 is due to the payment of expenses generated during the last half of 2007 for development activities. We have significantly decreased our development activities since the fourth quarter 2007.

Net cash used in investing activities was $121,000 for the year ended December 31, 2008, as compared to $3,612,000 provided by investing activities for the year ended December 31, 2007. The difference is primarily a result of net maturities of short-term investments in the year ended December 31, 2007.

Cash provided by financing activities was approximately $3,598,000 for the year ended December 31, 2008, as compared to $1,426,000 for the year ended December 31, 2007. On May 6, 2008, we entered into a binding securities purchase agreement with funds affiliated with ProQuest Investments LLC to sell up to $4,000,000 of secured convertible promissory notes, of which approximately $1,475,000 was funded on May 30, 2008 and the remaining $2,525,000 was funded on October 17, 2008. This was partially offset by financing costs of $238,000 related to the secured convertible notes. During the quarter ended June 30, 2007, we received net proceeds from private placements of $1,395,000.

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 drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs.

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

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

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

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

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

On May 14, 2008, we received notice from the NYSE Amex LLC indicating that we 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.

79

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

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

As of December 31, 2008, 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.

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

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

**OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

**CONTRACTUAL OBLIGATIONS**

The following table sets forth our aggregate contractual cash obligations as of December 31, 2008.

| | Payments Due By Period | | | | |
|---|---|---|---|---|---|
| | **Total** | **<1 year** | **1-3 years** | **3-5 years** | **5 years +** |
| Capital leases | $148,000 | $122,000 | $26,000 | $— | $— |
| Operating leases | 1,706,000 | 366,000 | 731,000 | 609,000 | — |
| Employment agreements | 840,000 | 800,000 | 40,000 | — | — |
| Total contractual cash obligations | $2,694,000 | $1,288,000 | $797,000 | $609,000 | $— |

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

We invest primarily in short-term, highly-rated investments, including U.S. government securities and certificates of deposit guaranteed by banks. Our market risk exposure consists principally of exposure to changes in interest rates. Because of the short-term maturities of our investments, however, we do not believe that a decrease in interest rates would have a significant negative impact on the value of our investment portfolio.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The financial statements required by this Item are included as a separate section of this report commencing on page F-1.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 9A(T). CONTROLS AND PROCEDURES.**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's, or SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of December 31, 2008. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of December 31, 2008, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework.*

Based on its evaluation, our management has concluded that, as of December 31, 2008, our internal control over financial reporting was effective. This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

**Changes in Internal Controls over Financial Reporting**

During the fourth quarter 2008, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

On October 17, 2008, the Company closed on the remaining portion (the "Subsequent Closing") of the 2008 private placement (the "2008 Financing") with ProQuest Investments.

With respect to the Subsequent Closing, the Company 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 Financing (the "Subsequent Registrable Shares") within 30 days of the closing. Also, the Company agreed to respond to all SEC comment letters as promptly as reasonably possible and to use its best efforts to have the registration statement declared effective within 90 days of the closing. However, the Company was unable to register 9,044,649 of the Subsequent Registrable Shares in accordance with the rules and regulations of the SEC. Therefore, the Company is filing the registration statement with the SEC to register the resale of 8,934,075 Subsequent Registrable Shares issuable pursuant to the 2008 Financing. There is no guarantee that the SEC will declare the registration statement effective. In connection with the Company's reduction of Subsequent Registrable Shares being registered on the registration statement, the Company has agreed with the purchasers to pay, as partial 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).

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

Certain of the information required to be disclosed by this Item with respect to our executive officers is set forth under the caption “Executive Officers and Directors” contained in Part I, Item 1 of this Annual Report on Form 10-K.

Certain information required to be disclosed by this Item about our board of directors is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Election of Directors,” and “Board of Directors and Committees” contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

Information required to be disclosed by this Item about our board of directors, the audit committee of our board of directors, our audit committee financial expert, our Business Conduct Policy, and other corporate governance matters is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Meetings and Committees of our Board” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

The text of our Business Conduct Policy, which applies to all of our directors, officers and employees is posted in the “Corporate Governance” section of our website, www.novadel.com. A copy of the Business Conduct Policy can be obtained free of charge on our website or can be obtained and will be provided to any person without charge upon written request to our Corporate Secretary at our executive offices, 25 Minneakoning Road, Flemington, New Jersey 08822. We intend to disclose on our website any amendments to, or waivers from, our Business Conduct Policy that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and NYSE Amex LLC.

**ITEM 11. EXECUTIVE COMPENSATION.**

Incorporated by reference to “Compensation Discussion and Analysis,” “Compensation Committee Report,” “Summary Compensation Table,” “Grants of Plan-Based Awards,” “Outstanding Equity Awards,” “Option Exercises and Stock Vested,” “Potential Payments Upon Termination” and “Directors Compensation” and “Compensation Committee Interlocks and Insider Participants” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

Incorporated by reference to “Stock Ownership of Directors, Management and Certain Beneficial Owners” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.**

Incorporated by reference to “Certain Relationships and Related Transactions” and “Independence of Directors” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

Incorporated by reference to "Independent Registered Public Accounting Firm's Fee Summary" contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2009, which we intend to file within 120 days of the end of our fiscal year (December 31, 2008).

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

(a) Financial Statements and Schedules:

1. Financial Statements

The following financial statements and report of independent registered public accounting firm are included herein:



2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

**INDEX TO EXHIBITS**

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

| EXHIBIT NO. | DESCRIPTION | METHOD OF FILING |
|---|---|---|
| 3.1 | Restated Certificate of Incorporation of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004 |
| 3.2 | Certificate of Amendment to the Certificate of Incorporation of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 3.3 | Amended and Restated By-laws of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Form 8-K, as filed with the SEC on September 9, 2005 |
| 4.1 | Form of Class C Warrant for the Purchase of Shares of Common Stock | Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 12, 2004 |
| 4.2 | Form of Warrant issued to certain accredited investors and placement agents | Incorporated by reference to Exhibit 4.1 of the Company's Form 8-K, as filed with the SEC on April 17, 2006 |
| 4.3 | Form of Warrant issued to certain accredited investors and the placement agent | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2007 |
| 4.4 | Form of Convertible Note | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 4.5 | Form of Warrant | Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 4.6 | Form of Liquidated Damages Notes | Filed herewith. |
| 10.1* | 1992 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.2* | Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.3* | 1997 Stock Option Plan | Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. |

| | | |
|---|---|---|
| | | 333-33201) |
| 10.4* | Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.5* | 1998 Stock Option Plan | Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |

| | | |
|---|---|---|
| 10.6* | Form of Stock Option Agreement under the 1998 Stock Option Plan | Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |
| 10.7* | Form of Non-Qualified Stock Option Agreement | Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |
| 10.8 | Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers | Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001 |
| 10.9 | Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers | Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement of Form SB-2, as filed with the SEC on April 15, 2002 (File No. 333-86262) |
| 10.10 | Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C. | Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003 |
| 10.11 | Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003 | Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003 |
| 10.12 | License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004 |
| 10.13 | Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc. | Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004 |
| 10.14 | Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc. | Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004 |
| 10.15* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney | Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |
| 10.16* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton | Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |
| 10.17* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |

| | | |
|---|---|---|
| 10.18* | Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer | Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004 |
| 10.19* | Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer | Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005 |

| | | |
|---|---|---|
| 10.20* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney | Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.21* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton | Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.22* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.23 | Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc. | Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005 |
| 10.24* | NovaDel Pharma Inc. 2006 Equity Incentive Plan | Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006 |
| 10.25* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell | Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.26* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.27* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.28* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.29* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff | Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.30* | Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |
| 10.31* | Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006 | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |
| 10.32* | Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006 | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |

| | | |
|---|---|---|
| 10.33* | Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with the SEC on February 28, 2007 |
| 10.34* | Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007 | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |

| | | |
|---|---|---|
| 10.35* | Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007 | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.36* | Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer | Incorporated by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.37* | Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007 | Incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.38* | Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007 | Incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.39 | Amended and Restated License and Development Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and HANA Biosciences, Inc. | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007. |
| 10.40 | Product Development and Commercialization Sublicense Agreement, dated as of July 31, 2007, by and among NovaDel Pharma Inc., HANA Biosciences and PAR Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with SEC on November 14, 2007. |
| 10.41 | Termination Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and PAR Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007. |
| 10.42* | Employment Agreement dated January 22, 2008, by and between the Company and Michael E. Spicer. | Incorporated by reference to Exhibit 10.50 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 31, 2008. |
| 10.43 | Securities Purchase Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.44 | Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.45 | Security and Pledge Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P., as secured partied and ProQuest Investments III, L.P. as collateral agent. | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.46+ | License Agreement, dated May 19, 2008, by and among the Company and BioAlliance Pharma SA. | Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 7, 2008. |

| | | |
|---|---|---|
| 10.47+ | Supply Agreement, dated July 7, 2008, by and among the Company and BioAlliance Pharma SA. | Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 7, 2008. |
| 21.1 | Subsidiaries of the Registrant | The registrant has no subsidiaries |
| 23.1 | Consent of J.H. Cohn LLP | Filed herewith |
| 31.1 | Certification of Chief Executive Officer under Rule 13a-14(a) | Furnished herewith |

| | | |
|---|---|---|
| 31.2 | Certification of Principal Financial Officer under Rule 13a-14(a) | Furnished herewith |
| 32.1 | Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350 | Furnished herewith |

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* Compensation Related Contract.
\+ Confidential Treatment Requested. Confidential Materials omitted and filed separately with the Securities and Exchange Commission.

(b) Exhibits.
See Item 15(a)(3) above.

(c) Financial Statement Schedules.
See Item 15(a)(2) above.

89

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NovaDel Pharma Inc.**

Date: March 30, 2009

By: /s/ STEVEN B. RATOFF
Steven B. Ratoff
Chairman, Interim President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| SIGNATURES | TITLE | DATE |
|---|---|---|
| /s/ STEVEN B. RATOFF<br>Steven B. Ratoff | Chairman, Interim President and Chief Executive Officer<br>(Principal Executive Officer) | March 30, 2009 |
| /S/ MICHAEL E. SPICER<br>Michael E. Spicer | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 30, 2009 |
| /S/ MARK J. BARIC<br>Mark J. Baric | Director | March 30, 2009 |
| /S/ THOMAS E. BONNEY<br>Thomas E. Bonney | Director | March 30, 2009 |
| /S/ WILLIAM F. HAMILTON<br>William F. Hamilton, Ph.D. | Director | March 30, 2009 |
| /S/ J. JAY LOBELL<br>J. Jay Lobell | Director | March 30, 2009 |
| /S/ CHARLES NEMEROFF<br>Charles Nemeroff | Director | March 30, 2009 |

91

**INDEX TO FINANCIAL STATEMENTS**

The following financial statements are included in Part II, Item 8:

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Stockholders and

Board of Directors

NovaDel Pharma Inc.

We have audited the accompanying balance sheets of NovaDel Pharma Inc. as of December 31, 2008 and 2007, and the related statements of operations, changes in stockholders' equity (deficit) and cash flows for the years then ended December 31, 2008 and 2007, the five months ended December 31, 2006 and for the fiscal year ended July 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. as of December 31, 2008 and 2007, and its results of operations 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, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. COHN LLP

Roseland, New Jersey

March 30, 2009

F-1

**NOVADEL PHARMA INC.**

**BALANCE SHEETS**

**AS OF DECEMBER 31, 2008 and 2007**

| ASSETS | December 31, 2008 | December 31, 2007 |
|---|---|---|
| Current Assets: | | |
| Cash and cash equivalents | $ 4,328,000 | $6,384,000 |
| Assets held for sale | 299,000 | 492,000 |
| Deferred financing costs, net of accumulated amortization of $213,000 | 25,000 | — |
| Prepaid expenses and other current assets | 958,000 | 1,146,000 |
| Total Current Assets | 5,610,000 | 8,022,000 |
| Property and equipment, net | 1,447,000 | 1,972,000 |
| Other assets | 259,000 | 369,000 |
| TOTAL ASSETS | $ 7,316,000 | $10,363,000 |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current Liabilities: | | |
| Secured convertible notes payable, net of unamortized discount of $403,000 | $ 3,597,000 | $— |
| Accounts payable | 654,000 | 1,632,000 |
| Accrued expenses and other current liabilities | 924,000 | 2,267,000 |
| Current portion of deferred revenue | 266,000 | 148,000 |
| Current portion of capital lease obligations | 122,000 | 164,000 |
| Total Current Liabilities | 5,563,000 | 4,211,000 |
| Non-current portion of deferred revenue | 4,468,000 | 1,830,000 |
| Non-current portion of capital lease obligations | 26,000 | 148,000 |
| Total Liabilities | 10,057,000 | 6,189,000 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Preferred stock, $.001 par value: | | |
| Authorized 1,000,000 shares, none issued | — | — |
| Common stock, $.001 par value: | | |
| Authorized 200,000,000 shares, Issued 60,692,260 and 59,592,260 at December 31, 2008 and 2007, respectively | 60,000 | 59,000 |
| Additional paid-in capital | 72,034,000 | 69,364,000 |
| Accumulated deficit | (74,829,000) | (65,243,000) |
| Less: Treasury stock, at cost, 3,012 shares | (6,000) | (6,000) |
| Total Stockholders' Equity (Deficit) | (2,741,000) | 4,174,000 |

| | | |
|---|---|---|
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | $ 7,316,000 | $ 10,363,000 |

See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**

**STATEMENTS 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**

| | Year Ended December 31, | | | Five Months Ended December 31, | | Year Ended July 31, |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 (unaudited) | 2006 | 2005 (unaudited) | 2006 |
| License Fees and Milestone Payments Earned from Related Parties | $ 361,000 | $ 469,000 | $ 3,162,000 | $ 2,067,000 | $ 568,000 | $ 1,662,000 |
| Consulting Revenues from Related Parties | — | — | 118,000 | — | 109,000 | 228,000 |
| Total Revenues | 361,000 | 469,000 | 3,280,000 | 2,067,000 | 677,000 | 1,890,000 |
| Research and Development Expenses | 3,878,000 | 11,940,000 | 6,589,000 | 3,396,000 | 2,082,000 | 5,275,000 |
| Consulting, Selling, General and Administrative Expenses | 4,722,000 | 6,716,000 | 6,955,000 | 3,123,000 | 3,347,000 | 7,179,000 |
| Loss on Assets Held for Sale | 351,000 | — | — | — | — | — |
| Total Expenses | 8,951,000 | 18,656,000 | 13,544,000 | 6,519,000 | 5,429,000 | 12,454,000 |
| Loss From Operations | (8,590,000) | (18,187,000) | (10,264,000) | (4,452,000) | (4,752,000) | (10,564,000) |
| Other, net | — | (66,000) | — | — | — | — |
| Interest Expense | (1,868,000) | — | — | — | — | — |
| Interest Income | 137,000 | 632,000 | 337,000 | 180,000 | 67,000 | 224,000 |
| Loss Before Income Tax Benefit | (10,321,000) | (17,621,000) | (9,927,000) | (4,272,000) | (4,685,000) | (10,340,000) |
| Income Tax Benefit | (735,000) | (658,000) | (467,000) | (467,000) | (256,000) | (256,000) |
| Net Loss | $ (9,586,000) | $ (16,963,000) | $ (9,460,000) | $ (3,805,000 | $ (4,429,000) | $ (10,084,000) |

)

| | | | | | | |
|---|---|---|---|---|---|---|
| Basic and Diluted Loss Per Common Share | $ (0.16 ) | $ (0.29 ) | $ (0.20 ) | $ (0.08 ) | $(0.11 ) | $ (0.23 ) |
| Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share | 59,592,000 | 59,497,000 | 46,732,000 | 49,522,000 | 40,619,000 | 43,000,000 |

See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

**FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007, THE FIVE MONTHS ENDED DECEMBER 31, 2006 AND THE FISCAL YEAR ENDED JULY 31, 2006**

| | Common Stock | | | | | | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Treasury Stock | Total Stockholders' Equity (Deficit) |
| BALANCE, August 1, 2005 | 40,597,318 | $ 41,000 | $42,305,000 | $ (34,391,000) | $ — | $ (6,000) | $ 7,949,000 |
| Share-based compensation expense | — | — | 1,201,000 | — | — | — | 1,201,000 |
| Stock issued in connection with private placements, net of costs | 8,092,796 | 8,000 | 10,585,000 | — | — | — | 10,593,000 |
| Stock issued for options and warrants exercised | 433,755 | — | 326,000 | — | — | — | 326,000 |
| Comprehensive income (loss): | | | | | | | |
| Unrealized gain on investment | — | — | — | — | 60,000 | — | 60,000 |
| Net loss | — | — | — | (10,084,000) | — | — | (10,084,000) |
| Total comprehensive loss | — | — | — | — | — | — | (10,024,000) |
| BALANCE, July 31, 2006 | 49,123,869 | 49,000 | 54,417,000 | (44,475,000) | 60,000 | (6,000) | 10,045,000 |
| Share-based compensation expense | 100,000 | — | 498,000 | — | — | — | 498,000 |
| Stock issued in connection with private placement, net of costs | 8,862,069 | 9,000 | 11,740,000 | — | — | — | 11,749,000 |
| Stock issued for options and warrants exercised | 272,880 | — | 205,000 | — | — | — | 205,000 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Comprehensive income (loss): | | | | | | | |
| Unrealized loss on investment in marketable equity security | — | — | — | — | (94,000) | — | (94,000) |
| Net loss | — | — | — | (3,805,000) | — | — | (3,805,000) |
| Total comprehensive loss | — | — | — | — | — | — | (3,899,000) |
| BALANCE, December 31, 2006 | 58,358,818 | 58,000 | 66,860,000 | (48,280,000) | (34,000) | (6,000) | 18,598,000 |
| Share-based compensation expense | — | — | 910,000 | — | — | — | 910,000 |
| Stock issued in connection with private placement, net of costs | 961,914 | 1,000 | 1,394,000 | — | — | — | 1,395,000 |
| Stock issued for options and warrants exercised | 271,528 | — | 200,000 | — | — | — | 200,000 |
| Comprehensive income (loss): | | | | | | | |
| Reclassification of unrealized loss on investment in marketable security to realized loss | — | — | — | — | 34,000 | — | 34,000 |
| Net loss | — | — | — | (16,963,000) | — | — | (16,963,000) |
| Total comprehensive loss | — | — | — | — | — | — | (16,929,000) |
| BALANCE, December 31, 2007 | 59,592,260 | 59,000 | 69,364,000 | (65,243,000) | — | (6,000) | 4,174,000 |
| Share-based compensation expense | — | — | 771,000 | — | — | — | 771,000 |
| Restricted stock issued | 1,100,000 | 1,000 | (1,000 | — | — | — | — |
| Warrants issued to investors and | — | — | 1,900,000 | — | — | — | 1,900,000 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| beneficial conversion feature embedded in convertible notes | | | | | | | |
| Net loss | — | — | — | (9,586,000) | — | — | (9,586,000) |
| BALANCE, December 31, 2008 | 60,692,260 | $ 60,000 | $ 72,034,000 | $ (74,829,000) | $ — | $ (6,000) | $ (2,741,000) |



See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**

**STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007, THE FIVE MONTHS ENDED DECEMBER 31, 2006 AND THE FISCAL YEAR ENDED JULY 31, 2006**

| | Year Ended December 31, | | Five Months Ended December 31, | | | Year Ended July 31, |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2006 | 2005 | 2006 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | | (unaudited) | | (unaudited) | |
| Net loss | $ (9,586,000) | $ (16,963,000) | $ (9,460,000) | $ (3,805,000) | $ (4,429,000) | $ (10,084,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | | | |
| Amortization of discount on short-term investments | — | (101,000) | (53,000) | (53,000) | — | — |
| Share-based compensation expense | 771,000 | 910,000 | 1,179,000 | 498,000 | 520,000 | 1,201,000 |
| Amortization of debt discount and deferred financing fees | 1,711,000 | — | — | — | — | — |
| Loss on assets held for sale | 351,000 | — | — | — | — | — |
| Loss on disposal of fixed assets | 19,000 | | | | | |
| Loss from return of investment in marketable security available-for-sale to issuer | — | 140,000 | — | — | — | — |
| Other than temporary impairment of investment in marketable equity security available-for-sale | — | 360,000 | — | — | — | — |
| Inventory reserve | — | — | 551,000 | 551,000 | — | 55,000 |
| Depreciation and amortization | 506,000 | 685,000 | 667,000 | 286,000 | 202,000 | 583,000 |
| Changes in operating assets and liabilities: | | | | | | |
| Accounts receivable from related parties | — | — | 76,000 | — | 32,000 | 108,000 |
| Inventories | — | (99,000) | (40,000) | 2,000 | 6,000 | (91,000) |
| Prepaid expenses and other current assets | 151,000 | (574,000) | (66,000) | (81,000) | (200,000) | (185,000) |
| Other assets | 110,000 | (10,000) | (8,000) | (15,000) | — | 7,000 |
| Accounts payable | (978,000) | 834,000 | 340,000 | (47,000) | (721,000) | (334,000) |
| Accrued expenses and other current liabilities | (1,344,000) | 206,000 | 212,000 | 950,000 | 785,000 | 47,000 |
| Deferred revenue | 2,756,000 | (628,000) | (162,000) | (68,000) | (68,000) | (162,000) |
| Net cash used in operating activities | (5,533,000) | (15,240,000) | (6,764,000) | (1,782,000) | (3,873,000) | (8,855,000) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | | | | |
| Purchases of property and equipment | (121,000) | (179,000) | (68,000) | (54,000) | (116,000) | (130,000) |
| Purchases of short-term and long-term investments | — | (9,737,000) | (5,761,000) | (1,310,000) | (1,300,000) | (5,751,000) |
| Maturities of short-term and long-term investments | — | 13,528,000 | 3,119,000 | 2,124,000 | 3,848,000 | 4,843,000 |
| Net cash provided by (used in) investing activities | (121,000) | 3,612,000 | (2,710,000) | 760,000 | 2,432,000 | (1,038,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | | | | |
| Proceeds from issuance of common stock through private placements | — | 1,395,000 | 22,342,000 | 11,749,000 | — | 10,593,000 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Proceeds from issuance of convertible notes | 4,000,000 | — | — | — | — | — |
| Deferred financing costs | (238,000) | — | — | — | — | — |
| Proceeds from options and warrants exercised | — | 200,000 | 531,000 | 205,000 | — | 326,000 |
| Payments of capital lease obligations | (164,000) | (169,000) | (52,000) | (33,000) | — | (19,000) |
| Net cash provided by financing activities | 3,598,000 | 1,426,000 | 22,821,000 | 11,921,000 | — | 10,900,000 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (2,056,000) | (10,202,000) | 13,347,000 | 10,899,000 | (1,441,000) | 1,007,000 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR OR PERIOD | 6,384,000 | 16,586,000 | 3,239,000 | 5,687,000 | 4,680,000 | 4,680,000 |
| CASH AND CASH EQUIVALENTS, END OF YEAR OR PERIOD | $ 4,328,000 | $ 6,384,000 | $ 16,586,000 | $ 16,586,000 | $ 3,239,000 | $ 5,687,000 |
| SUPPLEMENTAL DISCLOSURE OF CASH PAID FOR INTEREST | $ 28,000 | $ 37,000 | $ 7,000 | $ 4,000 | $ — | $ 3,000 |
| SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES: | | | | | | |
| Equipment acquired under capital lease obligations | $ — | $ 228,000 | $ 305,000 | $ 139,000 | $ — | $ 166,000 |

See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**

**NOTES TO FINANCIAL STATEMENTS**

**NOTE 1 - NATURE OF THE BUSINESS**

NovaDel Pharma Inc. (the "Company") is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed pharmaceuticals. The Company's proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. The Company's oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products, with the most advanced oral spray candidates targeting angina, nausea, insomnia, migraine headaches and disorders of the central nervous system.

To date, the Company has entered into strategic 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, the Company has 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™.

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

In July 2007, the Company entered into a Product Development and Commercialization Sublicense Agreement (the "Sublicense Agreement") with Hana Biosciences and Par Pharmaceutical, Inc. ("Par"), pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™ (the "Amended and Restated License Agreement") to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement. Also in July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies NitroMist™. For a five-year period that began November 18, 2004, INyX was to be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it would be INyX's responsibility to manufacture, package and supply NitroMist™ in such territories. Thereafter, INyX would have a non-exclusive right to manufacture such spray for an additional

five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company was informed by the trustees for INyX in June 2008 that the facility in Puerto Rico where manufacturing operations for NitroMist™ were conducted would be ceasing operations as of the end of July 2008. As a result, the Company selected an alternative contract manufacturing company, DPT Laboratories Inc ("DPT"), and is in the process of transferring manufacturing operations for NitroMist™ to DPT.

On June 28, 2006, the Company's Board of Directors approved a change of the Company's fiscal year end from July 31 to December 31. Accordingly, the new fiscal year began on January 1 and ended on December 31. Results of operations and the statement of cash flows presented for the year ended December 31, 2006 and the five months ended December 31, 2005 are unaudited as are all notes related thereto.

**NOTE 2 - LIQUIDITY AND BASIS OF PRESENTATION**

The Company has reported a net loss of $9,586,000, $16,963,000, $3,805,000 and $10,084,000 and negative cash flows from operating activities of $5,533,000, $15,240,000, $1,782,000 and $8,855,000 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, respectively. As of December 31, 2008, the Company had working capital of $47,000 and cash and cash equivalents of $4,328,000. Until and unless the Company's 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. The Company's long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs, or on terms favorable to it.

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, the Company requires capital to sustain its existing organization until such time as clinical activities can be resumed. The Company received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest Investments, and received $2,525,000 in gross proceeds on October 17, 2008, from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing mature on November 30, 2008 and, in the Subsequent Closing, mature on April 17, 2009. On November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders may either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at 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 the Company's assets, other than certain excluded assets. During the second quarter of 2008, the Company also entered into a European partnership for its ondansetron oral spray with BioAlliance, as a result of which it received an immediate non-refundable license fee of $3,000,000.

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

F-7

In addition, the Company has 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 it is 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 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note).

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

The Company's audited financial statements for the fiscal year ended December 31, 2008 were prepared under the assumption that the Company will continue our operations as a going concern. The Company was incorporated in 1982, and has a history of losses. As a result, the Company's independent registered public accounting firm in their audit report has expressed substantial doubt about the Company's ability to continue as a going concern. Continued operations are dependent on the Company's 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. The Company's financial statements do not include any adjustments that may result from the outcome of this uncertainty. If the Company cannot continue as a viable entity, its stockholders may lose some or all of their investment in the Company.

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

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

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

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

1003(a)(i).

F-8

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

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

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

**NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

REVENUE RECOGNITION – The Company receives revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

CASH EQUIVALENTS AND INVESTMENTS - Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. Investments include short-term investments and an investment in marketable common stock received from a licensee (Notes 9 and 10). Short-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit and US treasury securities with maturities when purchased greater than three months and less than one year. At times, such investments may be in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit.

FINANCIAL INSTRUMENTS - Financial instruments include cash and cash equivalents, short-term investments, and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

PROPERTY AND EQUIPMENT - Property and equipment, including leasehold improvements, are stated at cost. The Company provides for depreciation and amortization using the straight-line method, based upon estimated useful lives of five to ten years or the lease term, if shorter.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs are expensed as incurred.

INCOME TAXES - Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Temporary differences between financial statement and income tax reporting result primarily from net operating losses. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount. Deferred tax assets and liabilities are measured

using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is considered more likely than not that some portion or all of the deferred tax asset will not be realized.

DEFINED CONTRIBUTION RETIREMENT PLANS - During January 2004, the Company established a 401(k) retirement plan that is available to all employees and requires matching contributions by the Company. During the years ended December 31, 2008, 2007 and 2006, the five months ended December 31, 2006 and 2005, and the fiscal year ended July 31, 2006, the Company contributed approximately $69,000, $95,000, $96,000, $34,000, $39,000, and $101,000, respectively, to this plan. Prior to January 2004, the Company had a Simple IRA retirement plan, available to all employees that provided for contributions at management’s discretion.

INVENTORIES - Inventories, consisting of raw materials, are carried at the lower of cost or market. Cost is determined using the first-in, first-out (“FIFO”) method.

IMPAIRMENT OF LONG-LIVED ASSETS – In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (FAS 144), the Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the carrying amount of the asset and its estimated fair value. The Company has reviewed its long-lived property and equipment as of December 31, 2008, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

USE OF ESTIMATES – The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

LOSS PER SHARE – Loss per common share is computed pursuant to SFAS No. 128, "Earnings Per Share." Basic loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of December 31, 2008, December 31, 2007, December 31, 2006 and July 31, 2006, there were 48.0 million, 35.1 million, 38.4 million and 30.7 million common shares, respectively, issuable upon exercise of options and warrants, the vesting of non-vested restricted common stock, and the conversion of the convertible notes, which were excluded from the diluted loss per common share computation. Subsequent to December 31, 2008, in accordance with its remuneration practices, the Company issued an additional 2.2 million restricted shares, including (i) 1.9 million to existing executive officers and directors; and (ii) 262,500 to existing employees and certain consultants.

STOCK-BASED COMPENSATION - In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which revised "Accounting for Stock-Based Compensation," ("SFAS 123") and superseded Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," ("APB 25"), which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

The Company adopted the provisions of SFAS 123R effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. The Company adopted the modified prospective transition method which does not require restatement of prior periods. Instead, it requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Prior to the adoption of SFAS 123R, the Company applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for share-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended. The Company recorded share-based compensation of approximately $771,000 or $0.01 per share, $910,000 or $0.02 per share, and $1,179,000 or $0.03 per share, for the years ended December 31, 2008, 2007 and 2006, $498,000 or $0.01 per share, and $520,000 or $0.01 per share, for the five months ended December 31, 2006 and 2005, and $1,201,000, or $0.03 per share, for the fiscal year ended July 31, 2006. The Company will continue to incur share-based compensation charges in future periods. As of December 31, 2008, unamortized stock-based compensation expense of $1.5 million remains to be recognized, which is comprised of $391,000 related to non performance-based stock options to be recognized over a weighted average period of 1.4 years, $382,000 related to restricted stock to be recognized over a weighted average period of 1.9 years, and $727,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

NEW ACCOUNTING PRONOUNCEMENTS – In October 2008, the FASB issued FASB Staff Position No. SFAS 157-3, “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,” (“FSP 157-3”), to clarify the application of the provisions of SFAS 157 in an inactive market and how an entity would determine fair value in an inactive market. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The implementation of FSP 157-3 did not have a material effect on the Company’s results of operations or financial condition.

In May 2008, the FASB issued SFAS No. 162, “The Hierarchy of Generally Accepted Accounting Principles” (“SFAS 162”). SFAS 162 identifies a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with accounting principles generally accepted in the United States of America (“GAAP”). SFAS 162 is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles.” SFAS 162 is not expected to have a material impact on the Company’s results of operations or financial condition.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities – an amendment of FASB Statement No. 133” (“SFAS 161”). SFAS 161 expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities” (“SFAS 133”), to include how and why an entity uses derivative instruments, the accounting treatment for derivative instruments and hedging activity under SFAS 133 and related guidance, and how derivative instruments and hedged items affect an entity’s financial position, financial performance and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company will comply with the additional disclosure requirements upon adoption of SFAS No. 161.

In December 2007, the FASB issued SFAS No. 141R “Business Combinations” (“SFAS 141R”). SFAS 141R applies to all transactions or other events in which an entity obtains control of one or more businesses. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of SFAS 141R to have a material impact on its results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 160 “Noncontrolling Interests in Consolidated Financial Statements.” (“SFAS 160”) SFAS 160 applies to all entities that prepare consolidated financial statements, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS 160 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of SFAS 160 to have a material impact on its results of operations or on its financial condition.

F-11

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS 157”). SFAS 157 establishes a common definition for fair value to be applied to U.S. GAAP guidance requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. In February 2008, the FASB issued FASB Staff Position 157-2 (“FSP 157”) which delays the effective date of SFAS 157 for one year for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). SFAS 157 and FSP 157 are effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 did not have a material impact on the Company’s results of operations or financial condition. The Company is currently assessing the impact of FSP 157 for nonfinancial assets and liabilities.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities.” (“SFAS 159”) SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company did not elect the fair value option under SFAS 159 for eligible items that existed as of January 1, 2008.

In December 2007, FASB affirmed the conclusions of the Emerging Issues Task Force (EITF) on EITF Issue 07-1, “Accounting for Collaborative Arrangements” (“EITF 07-1”). EITF 07-1 requires collaborators to present the results of activities, for which they act as the principal, on a gross basis and report any payments received from or made to other collaborators based on other applicable GAAP or, in the absence of GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer relationship subject to EITF 01-9 “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”. EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-1 will have no material impact on its financial position or results of operations.

In June 2007, the FASB affirmed the conclusions of the EITF with respect to EITF Issue 07-3 “Accounting for Advance Payments for Goods or Services to be Used in Future Research and Development Activities” (“EITF 07-3”). EITF 07-3 concluded that non-refundable advance payments for future research and development activities pursuant to an executory contractual arrangement should be capitalized until the goods have been delivered or the related services performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-3 will have no material impact on its financial position or results of operations.

In June 2008, the FASB issued EITF 07-5, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock.” EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity’s own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, “Accounting For Derivative Instruments and Hedging Activities” and/or EITF 00-19, “Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock.” EITF 07-05 is effective as of the beginning of our 2009 fiscal year. As of January 1, 2009, the Company notes that the adoption of EITF 07-05 will result in a retrospective reclassification of the fair value of certain outstanding warrants from stockholders’ equity to liability in the amount of approximately $360,000. Additionally, the Company notes that upon adoption of EITF 07-05, the warrants will be marked to market at each reporting period. The warrants affected by the adoption of EITF 07-05 expired during the first quarter of 2009 and, as a result, the fair value of the warrant liability will be reduced to zero as of the end of the reporting period.

In May 2008, the FASB issued FASB Staff Position (“FSP”) APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement).” FSP APB14-1 will require us to account separately for the liability and equity components of our convertible debt. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate at the time of issuance. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires accretion of the resultant debt discount over the expected life of the debt. The FSP is effective for fiscal years beginning after December 15, 2008, and interim periods within those years. Entities are required to apply the FSP retrospectively for all periods presented. The Company does not expect the adoption of this FSP to have a material impact on its consolidated financial position or results of operations.

F-12

**NOTE 4 – CONVERTIBLE NOTES**

On May 6, 2008, the Company entered into a binding Securities Purchase Agreement by and among ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., referred to herein as the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company and the Purchasers, to sell up to $4,000,000 of secured convertible promissory notes, referred to herein as the convertible notes, and accompanying warrants to such Purchasers, referred to herein as the 2008 Financing. Mr. Steven Ratoff, the Company's Chairman, Interim President and Chief Executive Officer, is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments.

On May 30, 2008, the Company closed the initial portion of the transaction, referred to herein as the Initial Closing, for $1,475,000, representing no more than 5,000,000 shares of the common stock underlying the convertible notes, upon receipt of approval from the NYSE Amex LLC, and satisfaction of customary closing conditions. The 5,000,000 shares, along with the prior securities owned by the Purchasers, represented 19.8% of the Company's outstanding common stock upon execution of the Securities Purchase Agreement. At its Annual Stockholders' Meeting on September 8, 2008, the Company sought and received stockholder approval to fund additional amounts such that the total commitment, inclusive of the amount at the Initial Closing, equals up to $4,000,000, referred to herein as the Subsequent Closing and together with the Initial Closing, the Closings. On October 17, 2008, the Company closed the Subsequent Closing, for gross proceeds of $2,525,000.

In the Initial Closing, the Company issued the convertible notes, which convert into its common stock at a fixed price of $0.295 per share subject to certain adjustments, and five-year warrants to purchase 3,000,000 shares of its common stock, with an exercise price of $0.369 per share. The maturity date of the convertible notes issued in the Initial Closing is November 30, 2008.

In the Subsequent Closing, the Company issued the convertible notes, which convert into 10,744,681 shares of its common stock at a fixed price of $0.235 per share subject to certain adjustments, and five-year warrants to purchase 6,446,809 shares of its common stock, with an exercise price of $0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing is April 17, 2009. The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10%. All unpaid principal, together with any accrued but unpaid interest and other amounts payable under the convertible notes, shall be due and payable upon the earliest to occur of (i) when such amounts are declared due and payable by the Purchasers on or after the date that is 180 days after the date of issuance; or (ii) upon the occurrence of any change of control event. At the option of the Purchasers, interest may be paid in cash or in common stock of the Company. If the Company pays interest in common stock, the stock will be valued at the related conversion price for such convertible note. Therefore, on November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders could either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum. There can be no assurance whether the noteholders will convert their notes or demand immediate repayment of the convertible notes issued at maturity.

At its option, the Company can redeem without penalty or premium a portion of, or all of, the principal owed under the convertible notes by providing the Purchasers with at least 5 days' written notice; provided that the Purchasers shall retain conversion rights in respect of the convertible notes for such period of 5 days after the Company has given such notice. Each prepayment shall be accompanied by the payment of accrued and unpaid interest on the amount being prepaid, through the date of the prepayment.

The Company's obligations under the convertible notes are secured by all of its assets and intellectual property, with the exception of certain excluded assets, as evidenced by the Security and Pledge Agreement, executed on May 6, 2008. Excluded assets of the Company are (i) those assets that are the subject of its existing capital leases (approximately $472,000 in net book value of fixed assets as of December 31, 2008, on which $148,000 of capital lease obligations exist at December 31, 2008); (ii) the assets marked as "Assets held for sale" on its balance sheets as of December 31, 2008 and 2007, which represented assets associated with our NitroMist™ product which is currently being targeted for sale, the amount for which was $299,000 as of December 31, 2008; and (iii) the assets marked as "Other Assets" on its balance sheets as of December 31, 2008 and 2007, which represented restricted cash held as security for its letters of credit and leased assets, the amount for which was $259,000 as of December 31, 2008.

The conversion rate of each convertible note and the exercise price of the warrants are subject to adjustment for certain events, including dividends, stock splits and combinations.

The Company filed an initial registration statement with the SEC to register the resale of common stock issuable in connection with the Initial Closing (excluding interest shares), referred to herein as the initial registrable shares, on June 26, 2008, which registration statement became effective as of July 16, 2008. These registration rights will cease once the initial registrable shares are eligible for sale by the Purchasers without restriction under Rule 144. Upon certain events, the Company has agreed to pay as partial liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the Purchasers for any convertible notes then held by the Purchasers, but these payments may not exceed 10% of the aggregate purchase price paid by the Purchasers. With respect to the Subsequent Closing, the Company 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 Financing (the "Subsequent Registrable Shares") within 30 days of the closing. Also, the Company agreed to respond to all SEC comment letters as promptly as reasonably possible and to use its best efforts to have the registration statement declared effective within 90 days of the closing. However, the Company was unable to register 9,044,649 of the Subsequent Registrable Shares in accordance with the rules and regulations of the SEC. Therefore, the Company is filing the registration statement with the SEC to register the resale of 8,934,075 Subsequent Registrable Shares issuable pursuant to the 2008 Financing. There is no guarantee that the SEC will declare the registration statement effective. In connection with the Company's reduction of Subsequent Registrable Shares being registered on the registration statement, the Company has agreed with the purchasers to pay, as partial 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 10% per annum, and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). The Company has recognized a liability of $127,000 as of December 31, 2008 related to the partial liquidated damages for such subsequent registrable shares.

The Purchasers represented that they are "accredited investors" and agreed that the securities issued in the 2008 Financing bear a restrictive legend against resale without registration under the Securities Act. The convertible notes and warrants were sold pursuant to the exemption from registration afforded by Section 4(2) of the Securities Act and Regulation D thereunder.

Under EITF 00-27, "Application of Issue No. 98-5 to Certain Convertible Instrument," the value of the warrants issued to the investors is calculated relative to the total amount of the debt offering. The relative fair value of the warrants issued to the investors in the Initial Closing was determined to be $467,000, or 31.7% of the total offering. This was determined using the Black-Scholes Model and the following key assumptions were used: a discount rate of 3.41%, volatility of 80.26%, 5 year expected term, and dividend yield of 0%. The relative fair value of the warrants issued to the investors in the Subsequent Closing was determined to be $587,000, or 23.2% of the total offering. This was determined using the Black-Scholes Model and the following key assumptions were used: a discount rate of 2.30%, volatility of 88.55%, 5 year expected term, and dividend yield of 0%.

The relative fair value of the warrants issued in the Initial Closing (equaling $467,000) and the Subsequent Closing (equaling $587,000), along with the effective beneficial conversion feature of the debt in the Initial Closing of $743,000 and in the Subsequent Closing of $103,000 (each calculated as the difference between the conversion price specified in the Securities Purchase Agreement and the calculated intrinsic value of the conversion feature), total $1,900,000 and are not in excess of the face value of the debt. The Company is using the straight-line method to amortize the debt discount and beneficial conversion feature through the maturity dates of the convertible notes, which result does not differ materially from the effective interest rate method. For the year ended December 31, 2008, the Company has recorded additional interest expense of $1.5 million related to the amortization of the debt discount for the Initial Closing and the Subsequent Closing. To the extent the debt from the Initial Closing is converted prior to maturity the amortization of the debt discount will be accelerated.

The balance of the convertible debt as of December 31, 2008 is summarized as follows:

| | |
|---|---|
| Face amount | $ 4,000,000 |
| Total debt discount and beneficial conversion feature | 1,900,000 |
| Amortization of debt discount and beneficial conversion feature | 1,497,000 |
| Net unamortized debt discount and beneficial conversion feature | 403,000 |
| Net debt at December 31, 2008 | $ 3,597,000 |

Related to the issuance of the Initial Closing and the Subsequent Closing, the Company paid debt finance costs totaling $238,000, which were capitalized as deferred financing costs. These costs will be amortized into interest expense using the straight-line method, which result does not differ materially from the effective interest rate method. For the year ended December 31, 2008, the Company had recorded expense of approximately $213,000 related to the amortization of the deferred financing costs.

The $1,475,000 in gross proceeds from the Initial Closing, and the $2,525,000 in gross proceeds from the Subsequent Closing, were deposited into a new bank account with an account control agreement which provides that the bank will comply with the withdrawal requests originated by the Company without further consent by the Purchasers. However, if Purchasers notify the bank that the Purchasers will exercise exclusive control over the account due to an event of default on the convertible notes (a “Notice of Exclusive Control”), the bank is required to cease complying with withdrawal requests or other directions concerning the account originated by the Company. This agreement was signed by NovaDel, Purchasers and the bank. The parties entered into this agreement to perfect the Purchasers’ security interest in this account. There is no provision for the bank to monitor or restrict the use of proceeds for a particular purpose, absent a Notice of Exclusive Control as described above. Accordingly, this agreement is no different than any other collateral lien on assets. Therefore, the Company has classified these funds as part of cash and cash equivalents.

**NOTE 5 – ASSETS HELD FOR SALE**

The Company owns fixed assets with a net book value of $299,000, which are used in the production of its NitroMist™ product line. As of December 31, 2008, the Company was in discussions with several potential buyers for these assets. In accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” (“SFAS 144”), the Company has classified these assets as assets held for sale on the balance sheet. For the year ended December 31, 2007, the Company owned inventory of $131,000 related to the production of its NitroMist™ product line, which inventory was disposed of during the year ended December 31, 2008. During the year ended December 31, 2008, the Company wrote off $129,000 in inventory and $183,000 of the net property, plant and equipment, as a result of transferring manufacturing operations for NitroMist™ from its contract manufacturer in Manati, Puerto Rico, to its new contract manufacturer in Texas. The total amount of the inventory and equipment disposal, inclusive of $39,000 for the costs of such disposal, was recognized as a loss on disposal of assets held for sale of $351,000. In addition, the Company invested an additional $121,000 during the year ended December 31, 2008 for tooling related to its

NitroMist™ product line, which is located at the facility of its contract manufacturer for spray valves in England.

The assets held for sale are summarized as follows:

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| Inventory | $ — | $ 131,000 |
| Property, plant and equipment, net | 299,000 | 361,000 |
| Total assets held for sale | $ 299,000 | $ 492,000 |

**NOTE 6 - PROPERTY AND EQUIPMENT**

Property and equipment are summarized as follows:

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| Equipment | $ 2,164,000 | $ 2,183,000 |
| Furniture and fixtures | 455,000 | 455,000 |
| Leasehold improvements | 1,432,000 | 1,432,000 |
| | 4,051,000 | 4,070,000 |
| Less: Accumulated depreciation and amortization | 2,604,000 | 2,098,000 |
| | $ 1,447,000 | $ 1,972,000 |

Property and equipment as of December 31, 2008 and 2007 excludes gross fixed assets of $464,000 and $624,000, respectively, used in the production of its NitroMist™ product line. Accumulated depreciation as of December 31, 2008 and 2007 excludes accumulated depreciation of $165,000 and $263,000, respectively, on fixed assets used in the production of its NitroMist™ product line. Although such assets are on the premises of the Company's contract manufacturer for its NitroMist™ product line, such assets are the property of the Company and cannot be used by the contract manufacturer for any other business. In the event that the Company's contract with the contract manufacturer is terminated for any reason, such assets are to be returned to the Company. These assets have been reclassified as "Assets Held for Sale" on the balance sheets as of December 31, 2008 and 2007. See Note 5 for further information.

As of December 31, 2008 and 2007, the Company had total gross fixed assets of $513,000 and $627,000, with an accumulated depreciation of $93,000 and $80,000, respectively, recorded under a capital lease.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result

from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the carrying amount of the asset and its estimated fair value. The Company has reviewed its long-lived property and equipment as of December 31, 2008, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

**NOTE 7 - RELATED PARTY TRANSACTIONS**

PLACEMENT AGENT AGREEMENTS (see Note 8) – In January 2004, May 2005 and April 2006, the Company completed private placements for which it utilized Paramount BioCapital, Inc., or Paramount, as its placement agent or co-placement agent. Paramount and its affiliates are beneficial owners of a significant amount of shares of common stock and options and warrants for the purchase of shares of common stock of the Company and, accordingly, Paramount is a related party to the Company.

PRIVATE PLACEMENTS – On May 6, 2008, the Company entered into a binding Securities Purchase Agreement with ProQuest Investments (see Note 8), as amended, to sell up to $4,000,000 of secured convertible promissory notes and accompanying warrants to ProQuest Investments. As of March 20, 2009, ProQuest Investments, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 38.1% of our outstanding common stock (assuming the conversion of its secured convertible promissory notes and the exercise of certain warrants held by ProQuest Investments). As such, ProQuest Investments may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Interim President and Chief Executive Officer, has served as a venture partner with ProQuest Investments since December 2004, although he has no authority for investment decisions by ProQuest Investments.

COMPENSATION AND CONSULTING AGREEMENTS - In November 2005, the Company entered into a Confidential Separation Agreement and General Release (the “Separation Agreement”) and a Consulting Agreement (the “Consulting Agreement”) with Gary Shangold, M.D. Dr. Shangold is the former President and Chief Executive Officer of the Company. In December 2005, pursuant to the Separation Agreement, the Company paid Dr. Shangold a separation payment of $150,000. Pursuant to the Consulting Agreement, the Company paid Dr. Shangold $300,000 for the year ended December 31, 2006; $125,000 for the five months ended December 31, 2006; and $175,000 for the fiscal year ended July 31, 2006.

In September 2006, the Company’s Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff’s appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement is on a month-to-month basis and compensates Mr. Ratoff at a rate of $17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff approximately $210,000 and $207,000 for the years ended December 31, 2008 and 2007; and approximately $61,000 for the five months ended December 31, 2006. In March 2007, Mr. Ratoff’s monthly compensation was reduced to $10,000 to reflect his decreased day-to-day time involvement at the Company, and in June, 2007, Mr. Ratoff’s monthly compensation was increased to $17,500 per month to reflect his appointment as the Company’s Interim President and Chief Executive Officer.

In September 2007, in connection with his resignation, Dr. Egberts (the Company’s former Chief Executive Officer) and the Company entered into a Separation, Consulting and General Release Agreement (the “Agreement”). Pursuant to the Consulting Agreement, the Company paid Dr. Egberts approximately $223,000 and $140,000 for the years ended December 31, 2008 and 2007, respectively.

LICENSE AND DEVELOPMENT AGREEMENTS WITH RELATED PARTIES - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company’s proprietary oral spray technology to deliver propofol for pre-procedural sedation.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company’s proprietary oral spray technology in animals.

In October 2004, the Company entered into a license and development agreement (as amended in August 2005) with Hana Biosciences to develop and market the Company’s oral spray version of ondansetron. The agreement is an exclusive license for the U.S. and Canada. In July 2007, the Company 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™.

On May 19, 2008, the Company entered into an agreement with BioAlliance Pharma SA where BioAlliance acquired the European rights for NovaDel’s Ondansetron oral spray.

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 the Company's agreements with the parties to such agreements from time to time.

**NOTE 8 - STOCKHOLDERS' EQUITY (DEFICIT)**

PRIVATE PLACEMENTS – On May 6, 2008, the Company entered into a binding Securities Purchase Agreement by and among ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., referred to herein as the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company and the Purchasers, to sell up to $4,000,000 of secured convertible promissory notes, referred to herein as the convertible notes, and accompanying warrants to such Purchasers, referred to herein as the 2008 Financing. On May 30, 2008, the Company closed the initial portion of the transaction, referred to herein as the Initial Closing, for $1,475,000, representing 5,000,000 shares of the common stock underlying the convertible notes. On October 17, 2008, the Company closed the Subsequent Closing, for gross proceeds of $2,525,000, representing 10,744,681 shares of the common stock underlying the convertible notes (see Note 4).

In December 2006, the Company completed a private placement of 9,823,983 shares of common stock, at a purchase price of $1.45 per share and warrants to purchase up to approximately 3,929,593 shares of common stock at an exercise price of $1.70 per share. The Company received proceeds, net of offering costs, of $13,144,000 of which $11,749,000 was received in December 2006 and $1,395,000 was received in January 2007. As such, the Company issued 8,862,069 shares in December 2006 and 961,914 shares in January 2007 for this private placement.

Oppenheimer & Co. Inc. acted as the lead placement agent for this private placement, with Griffin Securities, Inc. acting as co-placement agent. The placement agents received compensation for acting as placement agents made up of cash compensation equal to 7% of the proceeds from the sale of the common stock, or $997,000, and warrants to purchase shares of common stock equal to 5%of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 491,199 shares (such warrants have the same terms as those issued to the investors), plus expenses. On the date of grant, the warrants had an approximate fair value of $0.89 per warrant. The Company agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

In April 2006, the Company closed a private placement of 8,092,796 shares of common stock and warrants to purchase a total of 2,427,839 shares of common stock with an exercise price of $1.60 per share of common stock. The Company received proceeds, net of offering costs, of approximately $10,593,000. Griffin Securities, Inc. and Paramount, a NASD broker-dealer, acted as the placement agents for this private placement. The placement agents were paid an aggregate fee for acting as placement agents of cash equal to 7% of the gross proceeds from the sale of the common stock, or $792,400, and warrants equal to 6% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 468,329 shares of common stock. Such warrants have the same terms as those issued to the investors. On the date of grant, the warrants had an approximate fair value of $0.92 per warrant. The placement agents were also entitled to a non-accountable expense allowance of up to $55,000 as reimbursement for out of pocket expenses incurred in connection with the offering. The Company agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

The Company has entered into registration rights agreements with certain holders of our common stock that require us to continuously maintain an effective registration statement covering the underlying shares of common stock. Such registration statements have been declared effective and must continuously remain effective for a specified term. If we fail to continuously maintain such registration statements as effective throughout the specified terms, the Company may be subject to liability to pay liquidated damages.

PREFERRED STOCK - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of the Preferred Stock has been designated or issued through December 31, 2007. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion and voting rights, and terms of redemption and liquidation.

**NOTE 9 - COMMITMENTS AND CONTINGENCIES**

EMPLOYMENT AGREEMENTS - At December 31, 2008, the Company had employment agreements with three officers of the Company providing for an aggregate salary of $800,000 and $40,000 in the years ending December 31, 2009 and 2010, respectively, excluding potential Company matching contributions to the officers' 401(k) plan. The remaining terms of the officers' employment agreements are outlined below. Generally, in the event an officer is terminated prior to the end of such agreement, the officer is entitled to severance payments equal to the officer's salary for the shorter of twelve months or the remaining term of the officer's employment agreement.

The employment agreements with the Company's officers are due to expire on the following schedule: Mr. Spicer's agreement in December 2009, Dr. Bergstrom's agreement in December 2009, and Mr. Zodda's agreement in February 2010.

In September 2007, in connection with his resignation, Dr. Egberts and the Company entered into a Separation, Consulting and General Release Agreement, pursuant to which the Company would have to pay Dr. Egberts fees for services at a rate of $363,000 per annum through July 25, 2008. At December 31, 2008, the Company had no further obligations to Dr. Egberts under the Agreement.

All of the foregoing employment agreements provide for the potential issuance of bonuses based on certain factors. Such agreements also provide for the grant of options to purchase shares of the Company's common stock.

LICENSE AND DEVELOPMENT AGREEMENTS - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first $125,000 of which was partially received during June 2003. In November 2003, the Company received $375,000 from Manhattan Pharmaceuticals for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. During the fiscal year ended July 31, 2005, the Company invoiced Manhattan Pharmaceuticals approximately $65,000 for the Company's reimbursable expenses.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's propriety oral spray technology in animals. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received an equity stake of 529,500 shares of common stock, approximately 15% at the time the shares were issued, in Velcera which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the fiscal years ended December 31, 2006, the five months ended December 31, 2005, and for the fiscal years ended July 31, 2006 and 2005, the Company invoiced Velcera approximately $119,000, $109,000, $228,000 and $183,000, respectively, for reimbursable expenses. Additionally, during the year ended December 31, 2007, and the fiscal year ended July 31, 2005, the Company invoiced Velcera $125,000 and $50,000, respectively, for contractual milestones that were reached.

In July 2004, the Company entered into a licensing agreement with Par for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the U.S. and Canada. The Company has received $250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement. In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™.

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences an exclusive license to develop and market the Company's oral spray version of ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences purchased 400,000 shares of the Company's common stock at a per share price equal to $2.50, a premium of $.91 per share or $364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the five months ended December 31, 2006 and the fiscal year ended July 31, 2006, the Company received $1,000,000 and $1,500,000, respectively, in milestone payments from Hana

Biosciences. During the year ended December 31, 2006, and for the fiscal years ended July 31, 2006 and 2005, the Company invoiced Hana Biosciences approximately $13,000, $13,000 and $84,000, respectively, for pass-through expenses incurred by the Company on behalf of Hana Biosciences.

In July 2007, the Company 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, the Company and Hana Biosciences amended and restated their existing license 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. The Company retains its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement.

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

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies NitroMist™. For a five-year period that began November 18, 2004, INyX was to be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it would be INyX's responsibility to manufacture, package and supply NitroMist™ in such territories. Thereafter, INyX would have a non-exclusive right to manufacture such spray for an additional five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company was informed by the trustees for INyX in June 2008 that the facility in Puerto Rico where manufacturing operations for NitroMist™ were conducted would be ceasing operations as of the end of July 2008. As a result, the Company selected an alternative contract manufacturing company, DPT Laboratories Inc ("DPT"), and is in the process of transferring manufacturing operations for NitroMist™ to DPT.

CAPITAL LEASE OBLIGATIONS – As of December 31, 2008, the Company has aggregate capital lease obligations of $148,000, of which $122,000, $22,000 and $4,000 are scheduled to be paid in the years ending December 31, 2009, 2010, and 2011, respectively.

OPERATING LEASES - In March 2003, the Company entered into a 10-year lease for office, laboratory, manufacturing and warehouse space. During the first five years of the lease, the annual rent is approximately $332,000 plus a proportionate share of real estate taxes and common area charges. Beginning in the sixth year and continuing through the tenth year of the lease, the annual rent will be approximately $366,000 plus a proportionate share of real estate taxes and common areas. Through December 31, 2005, the Company occupied office and laboratory space at a second location. During the years ended December 31, 2008, 2007 and 2006, the five months ended December 31, 2006 and 2005, and for the fiscal year ended July 31, 2006, the Company paid rent of approximately $453,000, $443,000, $456,000, $184,000, $223,000, and $495,000, respectively.

Future minimum rental payments subsequent to December 31, 2008 are as follows:

Years Ending December 31,

| | |
|---|---|
| 2009 | $366,000 |
| 2010 | 366,000 |
| 2011 | 366,000 |
| 2012 | 365,000 |
| 2013 | 243,000 |
| | $1,706,000 |

**NOTE 10 – INVESTMENT IN MARKETABLE EQUITY SECURITY**

As explained in Note 9, in October 2004, as part of the license agreement with Hana Biosciences, the Company received $500,000 of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share at the date of the agreement). As a result of restrictions on its ability to sell the shares, the Company was required by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," to account for those shares using the cost method through October 2005 and thereafter as marketable equity securities. At December 31, 2006, the Company had classified the shares as available for sale and recorded changes in their value as part of its comprehensive loss. Such shares had a market value of $466,000 at December 31, 2006 and, accordingly, the Company has included its $34,000 unrealized loss in accumulated comprehensive loss, a separate component of stockholders' equity, as of December 31, 2006.

As of March 31, 2007, such shares had a market value of $140,000, as compared to their original cost basis of $500,000. At such time, the Company determined that the decline in value of this investment was other than temporary and recorded a $360,000 impairment charge to the statement of operations, the only component of Other, net, for the three months ended March 31, 2007 to establish a new cost basis of $140,000 for the investment as of March 31, 2007. During the three months ended September 30, 2007, as a result of the Amended and Restated License Agreement with Hana Biosciences as described in Note 9, the Company recorded a $140,000 charge to expense that is included in Other, net, to account for the return of Hana Biosciences' shares. The combined non-cash charge of $500,000 for the year ended December 31, 2007 was recorded as Other, net. This amount was partially offset by a $434,000 benefit recognized to write off the remaining deferred revenue related to the shares received from Hana Biosciences, resulting in a net $66,000 expense for Other, net for the year ended December 31, 2007.

**NOTE 11 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities are comprised of the following at December 31, 2008 and 2007:

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| Accrued compensation | $ 40,000 | $ 397,000 |
| Professional fees | 60,000 | 131,000 |
| Accrued interest expense | 126,000 | — |
| Non-registration penalty | 127,000 | — |
| Product development costs | 437,000 | 1,558,000 |
| Insurance premiums | 129,000 | 167,000 |
| Other | 5,000 | 14,000 |
| | $ 924,000 | $ 2,267,000 |

**NOTE 12 - INCOME TAXES**

The significant components of the Company's net deferred tax asset are summarized as follows:

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| Stock-based compensation | $ 272,000 | $ 813,000 |
| Net operating loss carryforwards | 22,542,000 | 21,365,000 |
| Deferred revenue | 1,894,000 | 791,000 |
| Property and equipment | (166,000) | (147,000) |
| Research and development credit | 1,350,000 | 1,134,000 |
| Capital loss carryforwards | 200,000 | 200,000 |
| Accrued expenses and other reserves | 216,000 | 239,000 |
| Total gross deferred tax assets | 26,308,000 | 24,395,000 |
| Valuation allowance | (26,308,000) | (24,395,000) |
| Net deferred tax assets | $ — | $ — |

At December 31, 2008, the Company had federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately $61.8 million and $25.6 million, respectively, which can be used to offset current and future federal and state taxable income, if any, through 2028 and 2015, respectively. In addition, the Company has federal and state research and development tax credit of $0.9 million and $0.4 million, respectively, which will expire beginning 2020 and 2012, respectively. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has provided valuation allowances to offset its deferred tax assets due to the significant uncertainties related to its ability to generate future taxable income. The net increases in the total valuation allowance for the years ended December 31, 2008 and 2007, for the five-months ended December 31, 2006 and for the fiscal year ended July 31, 2006 were $1.9 million, $7.7 million, $0.8 million, and $4.0 million, respectively.

The tax benefits expected based on the Company's pre-tax loss for the years ended December 31, 2008, 2007 and 2006, for the five-months ended December 31, 2006 and 2005, and for fiscal year ended July 31, 2006, utilizing the applicable statutory rates, have been reduced to an actual benefit of $732,000, $658,000, $467,000, $467,000, $256,000 and $256,000, respectively, due principally to the aforementioned increases in the valuation allowance. The benefit recognized in such fiscal years relates solely to the sale of certain of the Company's state net operating loss carryforwards.

The following is a reconciliation of the income tax benefit computed at the statutory rate to the provision for income taxes:

| | Year Ended December 31, | | Five Months Ended December 31, | Year Ended July 31, |
|---|---|---|---|---|
| | December 31, 2008 | December 31, 2007 | 2006 | 2006 |
| Federal tax at statutory rate | (34.0%) | (34.0%) | (34.0%) | (34.0%) |
| State income tax | (6.0%) | (6.0%) | (6.0%) | (6.0%) |
| Other | 2.0% | 0.2% | (.3%) | — |
| Sale of net operating losses | (7.1%) | (3.7%) | (10.9%) | (2.5%) |
| Amortization of convertible debt discount | 5.4% | — | — | — |
| Cancelled stock option | 5.7% | — | — | — |
| Expired federal NOL | 1.1% | — | — | — |
| Increase in valuation allowance | 25.8% | 39.8% | 40.3% | 40.0% |
| | (7.1%) | (3.7%) | (10.9%) | (2.5%) |

The Tax Reform Act of 1986 (the “Act”) provides for a limitation on the annual use of NOL carryforwards (following certain ownership changes, as defined by the Act), which could significantly limit the Company’s ability to utilize these carryforwards. The Company has experienced various ownership changes, as defined by the Act, as a result of past financings and may experience others in connection with future financings. Accordingly, the Company’s ability to utilize the aforementioned federal operating loss carryforwards will be limited. The Company is in the process of determining the impact of ownership changes that have occurred, as defined by the Act. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes.

SALE OF NET OPERATING LOSS CARRYFORWARDS: The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The Company recorded an income tax benefit of $732,000, $658,000, $467,000, $467,000, $256,000 and $256,000 for the years ended December 31, 2008, 2007 and 2006, for the five months ended December 31, 2006 and 2005, and for the fiscal year ended July 31, 2006, respectively, from the sale of its New Jersey net operating loss carryforwards. If still available under New Jersey law, the Company may attempt to sell its remaining New Jersey net operating loss carryforwards of $25.6 million as of December 31, 2008. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner or at all.

The Company files income tax returns in the U.S. Federal jurisdiction and in the State of New Jersey. With certain exceptions, the Company is no longer subject to U.S. federal and state income tax examinations by tax authorities for years prior to 2004. However, NOL’s and tax credits generated from those prior years could still be adjusted upon audit. The Company adopted the provisions of FIN 48, “Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109” on January 1, 2007 with no material impact to the financial statements.

The Company had no unrecognized tax benefits at December 31, 2008 that would affect the annual effective tax rate. Further, the Company is unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

F-23

**NOTE 13 - STOCK OPTIONS AND WARRANTS**

At December 31, 2008, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan and the 2006 Equity Incentive Plan (the "Plans"). On January 17, 2006, the stockholders of the Company, upon recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the "2006 Plan"). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The number of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options ("ISOs") may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company's common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant, and vesting is determined by the Compensation Committee of the Board of Directors. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years. As of December 31, 2008, there were approximately 3.3 million shares available for issuance under the Plans. Subsequent to December 31, 2008, in accordance with its remuneration practices, the Company issued an additional 2.2 million stock options, including (i) 1.9 million to existing executive officers and directors; and (ii) 262,500 to existing and new employees (see Note 14).

The Company adopted the provisions of SFAS 123R effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R requires that compensation costs be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

Information with respect to stock option activity for the years ended December 31, 2008 and 2007, five months ended December 31, 2006 and for the fiscal year ended July 31, 2006 is as follows:

| Options | Shares (000) | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Terms (Years) | Aggregate Intrinsic Value ($000) |
|---|---|---|---|---|
| Outstanding at August 1, 2005 | 6,474 | $ 1.64 | — | $ — |
| Grants | 3,280 | 1.58 | — | — |
| Exercises | (360) | .75 | — | — |
| Forfeitures/Cancellations | (1,217) | 1.66 | — | — |
| Outstanding at July 31, 2006 | 8,177 | $ 1.65 | 4.4 | $ 492 |
| Exercisable at July 31, 2006 | 4,710 | $ 1.69 | 3.3 | $ 492 |
| Outstanding at August 1, 2006 | 8,177 | $ 1.64 | — | — |
| Grants | 900 | 1.71 | — | — |
| Exercises | (242) | .75 | — | — |
| Forfeitures/Cancellations | (60) | 1.56 | — | — |
| Outstanding at December 31, 2006 | 8,775 | $ 1.68 | 4.5 | $ 1,203 |
| Exercisable at December 31, 2006 | 5,313 | $ 1.73 | 3.1 | $ 973 |
| Outstanding at January 1, 2007 | 8,775 | $ 1.68 | — | — |
| Grants | 3,239 | 1.67 | — | — |
| Exercises | (268) | .75 | — | — |
| Forfeitures/Cancellations | (3,317) | 1.72 | — | — |
| Outstanding at December 31, 2007 | 8,429 | $ 1.69 | 5.9 | $ — |
| Exercisable at December 31, 2007 | 5,549 | $ 1.75 | 5.0 | $ — |
| Outstanding at January 1, 2008 | 8,429 | 1.69 | — | — |
| Grants | 338 | .24 | — | — |
| Exercises | — | — | — | — |
| Forfeitures/Cancellations | (3,300) | 1.72 | — | — |
| Outstanding at December 31, 2008 | 5,467 | $ 1.59 | 5.4 | $ — |
| Vested and expected to vest at December 31, 2008 | 5,349 | $ 1.59 | 5.4 | |
| Exercisable at December 31, 2008 | 3,102 | $ 1.74 | 4.2 | $ — |

F-25

The Company recorded share-based compensation for options using the fair value method required by SFAS 123R of approximately $771,000, or $0.01 per share, for the year ended December 31, 2008, $910,000, or $0.02 per share, for the year ended December 31, 2007; $1,179,000, or $0.03 per share, for the year ended December 31, 2006; $498,000 or $0.01 per share, for the five months ended December 31, 2006; $520,000, or $0.01 per share, for the five months ended December 31, 2005; and $1,201,000 or $0.03 per share, for the fiscal year ended July 31, 2006, which amounts are included in the Company's net loss for each period.

- On February 6, 2008, the Company's Board of Directors, upon the recommendation of the Compensation Committee, approved grants of 750,000 shares of restricted common stock to the executive officers of the Company and an additional 350,000 shares of restricted common stock to other employees of the Company. The restricted stock was awarded from the 1998 Stock Option Plan. The restrictions on the restricted stock shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a $5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional $5 million (or $10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a $20 million (or $20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse. Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of the Company's Chief Executive Officer, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a $5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional $5 million (or $10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares shall lapse over a three-year period.

- During the year ended December 31, 2008, the Company additionally granted 337,500 additional stock options. The exercise price of such options ranged from $0.21 per share to $0.24 per share.

- During the year ended December 31, 2007, the Company granted 3.2 million additional stock options, including 0.7 million options which vest upon reaching certain milestones. During the year ended December 31, 2007, the Company granted to an executive of the Company incentive stock options to purchase 68,027 shares of common stock of the Company and non-qualified stock options to purchase 598,973 shares of common stock of the Company. Such option grants have a term of ten (10) years. The stock options vest upon achievement of performance milestones; so that 22,676 incentive stock options and 200,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of sumatriptan; 22,676 incentive stock options and 199,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of zolpidem; and 22,675 incentive stock options and 199,325 non-qualified stock options will vest upon approval by the Board of any third party agreement whereby the Company obtains the right to develop a product incorporating an active pharmaceutical ingredient that is the subject of a then valid U.S. Patent (or in-process U.S. Patent Application) and already approved for sale by the U.S. Food and Drug Administration with sales in the U.S. of at least $100 million. Such options will expire on February 21, 2017. The exercise price of each option is $1.47 (the closing price of the Company's common stock on February 22, 2007, as listed on the NYSE Amex LLC (formerly known as the American Stock Exchange).

- During the five months ended December 31, 2006, the Company did not grant any additional stock options other than the December 2006 grant of 900,000 performance-based stock options which vest upon reaching certain milestones. Previously, the Company had not granted performance-based stock options. In addition, during the five months ended December 31, 2006, the Company granted 100,000 shares of restricted stock to an executive of the Company with a grant price equal to the fair market value on the date of grant, or $1.71 per share. The restricted stock vests ratably over a three-year period ending on the third anniversary of the grant, or December 4, 2009. Such performance-based stock options and restricted stock had a deminimus impact on the Company's net loss for the five months ended December 31, 2006, and resulted in recognition of $180,000 in share-based compensation expense for the year ended December 31, 2007. As of December 31, 2007, unamortized stock-based compensation expense of $2.0 million remains to be recognized, which is comprised of $1.2 million to be recognized over a weighted average period of 1.4 years, $0.1 million related to restricted stock to be recognized over a weighted average period of 1.9 years, and $0.7 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

The Company used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants in the respective periods:

| | Year Ended December 31, | | | Five Months Ended December 31, | Year Ended July 31, |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 (unaudited) | 2006 | 2006 |
| Expected volatility | 83% | 63% | 65% | 60% | 64% |
| Dividend yield | 0% | 0% | 0% | 0% | 0% |
| Expected term until exercise (years) | 3.7 | 4.9 | 3.9 | 2.5 | 4.5 |
| Risk-free interest rate | 2.3% | 4.8% | 4.5% | 4.4% | 4.3% |

Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, under SFAS 123R, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was $0.15, $0.93 and $0.84 during the years ended December 31, 2008, 2007 and 2006; $0.63 and $0.86 during the five months ended December 31, 2006 and 2005; and $0.86 during the fiscal year ended July 31, 2006. The total intrinsic value of options exercised was $172,000 and $398,000 during the years ended December 31, 2007 and 2006, $137,000 and $0 during the five months ended December 31, 2006 and 2005, and $261,000 for the fiscal year ended July 31, 2006. There were no options exercised during the year ended December 31, 2008.

At December 31, 2008, there were approximately 731,000 non-plan options reserved for issuance.

A summary of the status of the Company's non-vested restricted common stock as of December 31, 2008 and changes during the twelve months ended December 31, 2008 is presented below:

| Non-Vested Restricted Common Stock | Shares (000) | Weighted Average Grant-Date Fair Value |
|---|---|---|
| January 1, 2008 | 100 | $1.71 |
| Vested | (67) | $1.71 |
| Granted | 1,100 | $0.47 |
| December 31, 2008 | 1,133 | $0.51 |

The following table summarizes information related to warrants outstanding at December 31, 2008:

| Price Range | Number of Warrants Outstanding and Exercisable 000's | Remaining Contractual Life (Years) |
|---|---|---|
| $0.01 – 0.99 | 13,777 | 3.3 |
| $1.00 – 1.99 | 11,879 | 2.1 |
| Totals | 25,656 | |

**NOTE 14 – SUBSEQUENT EVENTS**

COMPENSATION - In connection with its annual review of executive compensation, on January 22, 2009, the Board of Directors (including a majority of the independent directors of the Board of Directors) of the Company approved, as recommended by the Compensation Committee of the Company, the proposal to maintain employee salaries, including the executive officers of the Company, at 2008 levels and to withhold annual bonuses for 2008 performance. Notwithstanding the foregoing, the Board of Directors (including a majority of the independent directors of the Board of Directors) of the Company approved, as recommended by the Compensation Committee of the Company, the proposal to grant a one-time special cash bonus of $50,000 to Dr. David H. Bergstrom in recognition of his individual efforts in 2008 in connection with the Company's research and development efforts and clinical activities including, but not limited to, the U.S. Food and Drug Administration's approval of the New Drug Application for Zolpimist (zolpidem tartrate) Oral Spray for the short-term treatment of insomnia.

In addition, on January 22, 2009, the Board of Directors (including a majority of the independent directors of the Board of Directors) of the Company approved, as recommended by the Compensation Committee of the Company, the proposal to grant stock options, in accordance with the Company's 2006 Equity Incentive Plan, to certain named executives as set forth below:

| Named Executive | Stock Option Award | Vesting |
|---|---|---|
| Steven B. Ratoff | 1,250,000 | (i) Options to purchase 450,000 shares of common stock are fully vested and exercisable on January 22, 2009. |
| | | (ii) Options to purchase 400,000 shares become fully vested and exercisable upon the Company's execution of license agreements whereby the Company will receive cumulative upfront payments of $2,500,000 or more. |
| | | (iii) Options to purchase 400,000 shares become fully vested and exercisable upon execution of license agreements whereby the Company will receive, inclusive of any upfront payment received in (ii) above, a total payment of $5,000,000 or more. |
| David H. Bergstrom | 400,000 | Exercisable in equal monthly installments over a period of twenty-four months. |
| Michael E. Spicer | 125,000 | Exercisable in equal monthly installments over a period of twenty-four months. |
| Deni M. Zodda | 125,000 | Exercisable in equal monthly installments over a period of twenty-four months. |

These options have an exercise price of $0.34 per share (equal to the fair market value on the date of grant, which is the closing price on January 22, 2009) and will expire on January 22, 2014.

In addition, on January 22, 2009, the Board of Directors (including a majority of the independent directors of the Board of Directors) of the Company approved, as recommended by the Compensation Committee of the Company, the proposal that, in the event that the Company engages in a strategic transaction, including a merger, sale, license, collaboration or other business combination, in which the Company will receive a payment or payments in excess of an undisclosed dollar amount approved by the Board of Directors, that Mr. Steven B. Ratoff will be granted a one-time special cash bonus of $500,000.

NYSE AMEX LLC – On January 30, 2009, the Company announced that it had been notified by the NYSE Amex LLC that they had granted the Company an extension until April 17, 2009 to regain compliance with Section 1003(a)(iv) of the NYSE Amex LLC Company Guide, and that the Company's deadline to regain compliance with Section 1003(a)(i), (ii) and (iii) remained November 16, 2009.

**NOTE 15 – QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

Unaudited quarterly financial data 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 follows:

| | Three Months Ended | | | | Year Ended |
|---|---|---|---|---|---|
| | March 31, 2008 | June 30, 2008 | September 30, 2008 | December 31, 2008 | December 31, 2008 |
| Total Revenues | $ 103,000 | $ 51,000 | $ 104,000 | $ 103,000 | $ 361,000 |
| Total Expenses | 2,110,000 | 2,987,000 | 1,878,000 | 1,976,000 | 8,951,000 |
| Loss from Operations | (2,007,000) | (2,936,000) | (1,774,000) | (1,873,000) | (8,590,000) |
| Interest Expense | — | 294,000 | 750,000 | 824,000 | 1,868,000 |
| Interest Income | 35,000 | 28,000 | 21,000 | 53,000 | 137,000 |
| Income Tax Benefit | — | — | — | 735,000 | 735,000 |
| Net Loss | $ (1,972,000) | $ (3,202,000) | $ (2,503,000) | $ (1,909,000) | $ (9,586,000) |
| Basic and Diluted Loss Per Common Share | $ (0.03) | $ (0.05) | $ (0.04) | $ (0.03) | $ (0.16) |
| Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share | 59,592,000 | 59,592,000 | 59,592,000 | 59,592,000 | 59,592,000 |

| | Three Months Ended | | | | Year Ended |
|---|---|---|---|---|---|
| | March 31, 2007 | June 30, 2007 | September 30, 2007 | December 31, 2007 | December 31, 2007 |
| Total Revenues | $ 40,000 | $ 165,000 | $ 206,000 | $ 58,000 | $ 469,000 |
| Total Expenses | 5,334,000 | 5,676,000 | 3,037,000 | 4,609,000 | 18,656,000 |
| Loss from Operations | (5,294,000) | (5.511,000) | (2,831,000) | (4,551,000) | (18,187,000) |
| Other Income/(Loss) | (360,000) | — | 294,000 | | (66,000) |
| Interest Income | 230,000 | 187,000 | 127,000 | 88,000 | 632,000 |
| Income Tax Benefit | — | — | — | 658,000 | 658,000 |
| Net Loss | $ (5,424,000) | $ (5,324,000) | $ (2,410,000) | $ (3,805,000) | $ (16,963,000) |
| Basic and Diluted Loss Per Common Share | $ (0.09) | $ (0.09) | $ (0.04) | $ (0.06) | $ (0.29) |
| Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share | 59,264,000 | 59,537,000 | 59,591,000 | 59,592,000 | 59,497,000 |

The sum of the quarters may not equal the full year basic and diluted loss per share since each period is calculated separately.

**INDEX TO EXHIBITS**

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

| EXHIBIT NO. | DESCRIPTION | METHOD OF FILING |
|---|---|---|
| 3.1 | Restated Certificate of Incorporation of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004 |
| 3.2 | Certificate of Amendment to the Certificate of Incorporation of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 3.3 | Amended and Restated By-laws of the Company | Incorporated by reference to Exhibit 3.1 of the Company's Form 8-K, as filed with the SEC on September 9, 2005 |
| 4.1 | Form of Class C Warrant for the Purchase of Shares of Common Stock | Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 12, 2004 |
| 4.2 | Form of Warrant issued to certain accredited investors and placement agents | Incorporated by reference to Exhibit 4.1 of the Company's Form 8-K, as filed with the SEC on April 17, 2006 |
| 4.3 | Form of Warrant issued to certain accredited investors and the placement agent | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2007 |
| 4.4 | Form of Convertible Note | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 4.5 | Form of Warrant | Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 4.6 | Form of Liquidated Damages Notes | Filed herewith. |
| 10.1* | 1992 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.2* | Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.3* | 1997 Stock Option Plan | Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. |

| | | |
|---|---|---|
| | | 333-33201) |
| 10.4* | Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan | Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201) |
| 10.5* | 1998 Stock Option Plan | Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |

| | | |
|---|---|---|
| 10.6* | Form of Stock Option Agreement under the 1998 Stock Option Plan | Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |
| 10.7* | Form of Non-Qualified Stock Option Agreement | Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665) |
| 10.8 | Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers | Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001 |
| 10.9 | Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers | Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement of Form SB-2, as filed with the SEC on April 15, 2002 (File No. 333-86262) |
| 10.10 | Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C. | Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003 |
| 10.11 | Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003 | Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003 |
| 10.12 | License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004 |
| 10.13 | Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc. | Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004 |
| 10.14 | Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc. | Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004 |
| 10.15* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney | Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |
| 10.16* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton | Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |
| 10.17* | Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005 |
| 10.18* | | |

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| | Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer | Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004 |
| 10.19* | Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer | Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005 |

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| 10.20* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney | Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.21* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton | Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.22* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005 |
| 10.23 | Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc. | Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005 |
| 10.24* | NovaDel Pharma Inc. 2006 Equity Incentive Plan | Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006 |
| 10.25* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell | Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.26* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.27* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.28* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff | Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.29* | 1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff | Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006 |
| 10.30* | Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |
| 10.31* | Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006 | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |
| 10.32* | Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006 | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006 |
| 10.33* | Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with |

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| | | the SEC on February 28, 2007 |
| 10.34* | Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007 | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.35* | Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007 | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |

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| 10.36* | Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer | Incorporated by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.37* | Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007 | Incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.38* | Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007 | Incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007 |
| 10.39 | Amended and Restated License and Development Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and HANA Biosciences, Inc. | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007. |
| 10.40 | Product Development and Commercialization Sublicense Agreement, dated as of July 31, 2007, by and among NovaDel Pharma Inc., HANA Biosciences and PAR Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with SEC on November 14, 2007. |
| 10.41 | Termination Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and PAR Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007. |
| 10.42* | Employment Agreement dated January 22, 2008 by and between the Company and Michael E. Spicer. | Incorporated by reference to Exhibit 10.50 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 31, 2008. |
| 10.43 | Securities Purchase Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.44 | Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P. | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.45 | Security and Pledge Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P., as secured partied and ProQuest Investments III, L.P. as collateral agent. | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008. |
| 10.46+ | License Agreement, dated May 19, 2008, by and among the Company and BioAlliance Pharma SA. | Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 7, 2008. |
| 10.47+ | Supply Agreement, dated July 7, 2008, by and among the Company and BioAlliance Pharma SA. | Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 7, 2008. |
| 21.1 | Subsidiaries of the Registrant | The registrant has no subsidiaries |

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| 23.1 | Consent of J.H. Cohn LLP | Filed herewith |
| 31.1 | Certification of Chief Executive Officer under Rule 13a-14(a) | Furnished herewith |
| 31.2 | Certification of Principal Financial Officer under Rule 13a-14(a) | Furnished herewith |
| 32.1 | Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350 | Furnished herewith |

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* Compensation Related Contract.

\+ Confidential Treatment Requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.