NOVADEL PHARMA INC
Form 10-K
March 31, 2010

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, 2009

OR

[ ] TRANSITION 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.)

1200 ROUTE 22 EAST, SUITE 2000, BRIDGEWATER, NEW JERSEY 08807
(Address of principal executive offices) (Zip Code)

(908) 203-4640
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	OTCBB

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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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. x

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 ¨ (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, 2009, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $17 million based upon the closing sale price of $0.31 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 24, 2010, the issuer had 89,283,000 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, 2009) are incorporated by reference into Part III of this Annual Report on Form 10-K.

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NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2009

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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.

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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, insomnia, erectile dysfunction, migraine headaches, nausea 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 nine patents which have been issued in the U.S. and 69 patents which have been issued outside of the U.S. Additionally, we have over 65 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, 2009 of $82,766,000, as compared to $74,829,000 as of December 31, 2008. Additionally, we have had negative cash flow from operating activities of $1,578,000 for the year ended December 31, 2009, $5,533,000 for the year ended December 31, 2008, and $15,240,000 for the year ended December 31, 2007. As of December 31, 2009, we had negative working capital of $495,000 as compared to $47,000 as of December 31, 2008, representing a net decrease in working capital of approximately $542,000.

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Throughout 2009, our reduced clinical development activities were limited to expenditures required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products. We will seek to raise additional capital in 2010 to fund our operations and future development activities 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. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010. We will need additional financing thereafter until we achieve profitability.

Our audited financial statements for the year ended December 31, 2009 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 our financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 and 2011will 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.

As previously disclosed 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. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

Highlights for the year ended December 31, 2009, 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

- After careful review of our portfolio of product opportunities we have selected Sildenafil Citrate (Viagra®) as our next product to develop. Our development plans anticipate that our oral spray formulation, Duromist™, will be available for launch in the first half of 2012.

Intellectual Property

- Announced that we received a Notice of Allowance from the United States Patent and Trademark Office, or USPTO, for claims under U.S. Patent Application No. 10/671,715, entitled “Buccal, Polar and Non-polar Spray Containing Zolpidem,” which covers a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. Once issued, this patent will expire in 2018.

- Announced that we received an Issue Notification from the USPTO for a new U.S. Patent, No. 7632517, entitled “Buccal, Polar and Non-polar Spray Containing Zolpidem,” which covers a method of treating insomnia by administering zolpidem to humans utilizing NovaDel's oral spray technology.

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Other

- Announced that Michael E. Spicer resigned as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. Our Board of Directors appointed Deni M. Zodda, Ph.D., 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.

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

- Announced the Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010. Mr. Ratoff will continue to serve as Interim Chief Financial Officer.

- Announced we executed a lease amendment modifying certain terms to the lease for the property in Flemington, New Jersey. The amendment converted the lease term to month to month commencing on July 1, 2009 with a provision that either party may terminate the lease upon thirty days written notice. We have released the lease escrow of $226,000 to the landlord in order to satisfy rent payments through June 30, 2009. This lease was terminated in December 2009.

- Effective February 1, 2010, we entered into a one (1) year lease agreement with Regus Management Group LLC for approximately 5,000 square feet of office space in Bridgewater, New Jersey.

- Announced that we entered into an agreement with Seaside 88, LP, or Seaside. Under the terms of the agreement and subject to the approval of the NYSE Amex LLC, Seaside has committed to purchase up to 13.0 million NovaDel common shares, in a series of closings every two weeks in the amount of 500,000 shares each for a total of up to 26 purchases. We had received approval from NYSE Amex LLC to issue up to 12.0 million shares over twelve (12) months. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

- Announced we entered into an agreement with Arthur W. Wood Company, Inc., or AWW, pursuant to which AWW agreed to assist us as a non-exclusive financial advisor for the purposes of seeking capital related to the Seaside offering, referred to herein as the Placement. In consideration of AWW's services, we agreed to pay AWW upon closing of a capital-raising transaction, a fee equal to three percent (3%) of the aggregate value of the proceeds paid or payable in the Placement.

- Announced we received a milestone payment of approximately $150,000 from Velcera, Inc., or Velcera, relating to its License and Development Agreement with Velcera, dated June 22, 2004.

- Announced we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales, subject to the terms of the agreement.

- Announced we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ product in the United States and Canada. ZolpiMist™ is our oral

spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, we received $3,000,000 upon the execution of the agreement and ECR will pay us ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement.

- Announced that we notified NYSE Amex LLC of our intent to voluntarily delist our common stock from the Exchange. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. Our common stock began trading on the OTCBB on December 24, 2009. Our new ticker symbol on OTCBB is NVDL.OB.

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- Announced we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock as of December 31, 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. We anticipate generating revenues in 2010 from our existing licensed products, Zolpimist™ and NitroMist™. 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.

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We expect to spend significant amounts on the development of certain of our product candidates and we expect our costs to increase if we restart certain 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	Mist Acquisition, LLC
Zolpimist™	zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals Company
Product Candidates				
Duromist™	sildenafil	Erectile Dysfunction	Preclinical development	-
Zensana™	ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.
NVD-201	sumatriptan	Migraines	Pilot Efficacy study complete	-
NVD-301	midazolam	Pre-Procedure Anxiety	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. On October 27, 2009, we entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC, or Mist, to manufacture and commercialize the NitroMist™ in the United States, Canada and Mexico. Under the terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement, and will pay us milestone payments totaling an additional $1,000,000 over the next twelve months if certain milestones are met and ongoing performance payments of up to seventeen percent (17%) of net sales. In addition, Mist will assume the activities and costs necessary for the completion of the product transfer to DPT Laboratories.

Zolpimist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic for insomnia marketed by Sanofi-Aventis. Our oral spray formulation of zolpidem was approved for the short-term treatment of insomnia by the FDA in December 2008. In October 2009, we received a Notice of Allowance from the United States

Patent and Trademark Office, or USPTO for claims which cover a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

Duromist™ (Sildenafil oral spray). Duromist™ 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 2010, with a development plan that would deliver a FDA approved product available for launch in the second quarter of 2012.

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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 have notified Hana and Par that under the terms of our agreement, they are required to return the product to us.

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 that their development activities will not be initiated until development is completed in the United States.

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.

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

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

We believe NVD-201 may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, we believe NVD-201 may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due to funding constraints and other higher priorities associated with our current product pipeline, we have not progressed our development efforts.

We will continue to evaluate this program when sufficient additional funding becomes available.

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.

As of the current date, we have not yet secured sufficient financing to resume our 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.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. On July 10, 2007, Manhattan Pharmaceuticals, our licensee, 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. On August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. This milestone payment resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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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) Mist Acquisition, LLC to manufacture and commercialize the NitroMist® lingual spray version of nitroglycerine, (ii) ECR Pharmaceuticals Company, Inc., to commercialize and manufacture ZolpiMist™ in the United States and Canada, (iii) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for our ondansetron oral spray, (iv) Par, for the marketing rights in the U.S. and Canada for NitroMist™, (v) Manhattan Pharmaceuticals, in connection with propofol, (vi) Velcera, in connection with veterinary applications for currently marketed veterinary drugs and (vii) 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™.

We intend to enter into additional license agreements and strategic alliances, including 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 Product Development and Commercialization Sublicense Agreement, or the Sublicense Agreement, with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, Hana Biosciences amended and restated their existing License and Development Agreement, as amended, with us relating to the development and commercialization of Zensana™, referred to herein as the Amended and Restated License Agreement, to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. We retain our rights to Zensana™ outside of the United States and Canada.

In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock, with a fair value of $140,000, that had been acquired by us in connection with execution of the original License Agreement (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.

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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™.

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.

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, 2009. 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 August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to its license agreement. This milestone payment resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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. 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, 2009, we recognized $38,000 and $154,000 of income related to this contract, respectively.

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AGREEMENT WITH MIST ACQUISITION, LLC

On October 27, 2009, we and privately-held Mist Acquisition, LLC, entered into a licensing agreement to manufacture and commercialize the NitroMist® lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement, and will pay milestone payments totaling an additional $1,000,000 over twelve months if certain conditions are met, and ongoing performance payments of seventeen percent (17%) of net sales, subject to the terms of the agreement.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist® in North America. NitroMist® provides acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The lingual spray form of the drug is conveniently administered and is rapidly absorbed into the bloodstream via the oral mucosa, providing patients a fast and tolerable treatment option for the prevention or relief of pain associated with such attacks.

AGREEMENT WITH ECR PHARMACEUTICALS COMPANY, INC.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. (a wholly-owned subsidiary of Hi-Tech Pharmacal Co., Inc.) to commercialize and manufacture ZolpiMist™ in the United States and Canada. ZolpiMist™ is the Company’s oral spray formulation of zolpidem tartrate approved by the FDA in December of 2008.

Under the terms of the agreement, we received a $3,000,000 licensing fee from ECR upon execution of the agreement. ECR will assume responsibility for manufacturing and marketing the product in the United States and Canada. In addition, ECR will pay royalties of up to 15% on net sales of ZolpiMist™ as well as an additional milestone payment if sales reach a specified level.

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 four product candidates in our pipeline. Our NitroMist™ and Zolpimist™ products are approved and currently licensed to Mist Acquisition, LLC and ECR Pharmaceuticals Company, Inc., respectively. Zensana™, is currently licensed to a marketing partner who we expect to commercialize this product candidate, with us receiving milestone and royalty income from revenue upon product approval. 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.

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PATENTED AND PATENT PENDING DELIVERY SYSTEMS

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

MARKETING AND DISTRIBUTION

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

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

In as much as we do not currently 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. 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.”

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 certain of our products. Rechon provides these services on a fee-for-service basis.

On December 28, 2009, DPT Laboratories became our contract manufacturer for Duromist™, sildenafil citrate oral spray.

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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.

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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.

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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.

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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.

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.

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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 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. Currently, we have nine patents which have been issued in the U.S. and 69 patents which have been issued outside of the U.S. Additionally, we have over 65 patents pending around the world. 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.

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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.

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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/Nonpolar 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.

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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.

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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.

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.

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.

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 24, 2010, we had 3 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 and Mr. Warusz.

NAME	AGE	POSITION WITH THE COMPANY
Mark J. Baric	51	Director
Thomas E. Bonney	45	Director
Charles Nemeroff, M.D., Ph.D.	60	Director
Steven B. Ratoff	67	Chairman of the Board of Directors, President, Chief Executive Officer and Interim Chief Financial Officer
David H. Bergstrom, Ph.D.	55	Senior Vice President and Chief Operating Officer
Joseph M. Warusz	53	Principal Accounting Officer

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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 2009, Deni Zodda, Ph.D. served as Interim Chief Financial Officer and Corporate Secretary and Joseph M. Warusz, a consultant, shall serve as Principal Accounting Officer. On April 28, 2009, Steven Ratoff was appointed Interim Chief Financial Officer and Corporate Secretary concurrent with the resignation of Deni Zodda.

Mark J. Baric, Director, 51. 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 our chair of our Corporate Governance and Nominating Committee, and a member of our Audit and Compensation Committees.

Thomas E. Bonney, CPA, Director, 45. 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 our lead director, chair of our Audit Committee and a member of our Compensation and Corporate Governance and Nominating Committees.

Charles Nemeroff, M.D., Ph.D., Director, 60. Dr. Nemeroff was elected to the Board in September 2003. Dr. Nemeroff is the Leonard M. Miller Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the University of Miami Leonard M. Miller School of Medicine in Miami, Florida since 2009. Previously, he served as the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia. Dr. Nemeroff has served on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals and Forest Laboratories. 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, and his M.D., Ph.D. and post doctoral training from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory Board. He is also chair of our Compensation Committee and a member of our Audit and Corporate Governance and Nominating Committees.

Steven B. Ratoff, Chairman of the Board, President, Chief Executive Officer, Interim Chief Financial Officer and Secretary, 67. 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. On December 31, 2009, he was appointed President and Chief Executive Officer. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest, a health care venture capital firm. Mr. Ratoff served as 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 which has recently merged with Raptor. 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 manufacturer and marketer of alcoholic beverages. Mr. Ratoff also was employed by Bristol Myers Squibb from 1975 to 1991, serving in a number of executive positions, the last of which was as Senior Vice President and Chief Financial Officer of the Pharmaceutical Group. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

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David H. Bergstrom, Ph.D., Senior Vice President and Chief Operating Officer, 55. 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.

Joseph M. Warusz, Principal Accounting Officer, 53. Mr. Warusz joined NovaDel as a consultant in April 2009, serving as Principal Accounting Officer. Since March 2006, Mr. Warusz has been providing consulting services to a broad range of clients in the life sciences sector. From August 2005 to March 2006, Mr. Warusz was Vice President, Finance, of Orchid Cellmark Inc. (formerly known as Orchid Biosciences, Inc.). Mr. Warusz is a Certified Public Accountant and holds an undergraduate degree in accounting and an MBA from Drexel University.

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 jwarusz@novadel.com or contact Joseph Warusz, our Principal Accounting Officer, at 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey, 08807or at 908-203-4643.

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.

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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, 2009, 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 on our 2009 Financial Statements 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 financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.

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

We have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing throughout 2009, limiting our expenditures primarily to those required to support our two approved products NitroMist™ and Zolpimist™. We have initiated product development of Duromist™, an oral spray of sildenafil citrate, for the treatment of erectile dysfunction. 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, to complete the development of this product and other products in our product development pipeline.

On October 27, 2009, we entered into a licensing agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and we will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

In addition, on December 31, 2009, we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal

to $3,657,000 to 23,237,083 shares of our common stock as of December 31, 2009.

We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

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We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

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

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

We are seeking to raise additional capital in 2010 to fund our operations and future development. A capital raise 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.

If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

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, negative 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, license agreements and sale of equity securities. 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. 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 2009, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities.

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, however our licensees for Nitromist and Zolpimist are expected to commercially launch these products in the second half of 2010. 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. 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.

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We had an accumulated deficit as of December 31, 2009 of approximately $82,766,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $7,577,000 for the year ended December 31, 2009, $9,586,000 for the year ended December 31, 2008, and $16,963,000 for the year ended December 31, 2007. Additionally, we have reported negative cash flows from operations of approximately $1,578,000 for the year ended December 31, 2009, $5,533,000 for the year ended December 31, 2008, and $15,240,000 for the year ended December 31, 2007. 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 24, 2010, ProQuest, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 40.6% of our outstanding common stock (assuming full exercise of certain warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Chairman, President, Chief Executive Officer and Interim Chief Financial Officer, has served as a venture partner with ProQuest since December 2004, although he has no authority for investment decisions by ProQuest.

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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.

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 obtaining regulatory approvals for and licensing our product candidates. We anticipate that marketing activities by our licensees for our two approved products, will not begin until the second half of 2010.

There can be no assurances that our licensees will successfully market out two approved product candidates, or that such product candidates will become commercially available.

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. We have recently obtained strategic partners for both NitroMist™ and Zolpimist™. 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.

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 Mist, ECR, BioAlliance, 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.

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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.

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.

On December 28, 2009, DPT Laboratories became our contract manufacturer for Duromist, sildenafil citrate oral spray.

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 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.

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

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

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

WE FACE INTENSE COMPETITION.

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

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

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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.

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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™ and ZolpiMist™, 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 December 31, 2008, we 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. Subsequent to December 31, 2008, the following events occurred with respect our strategic license agreements:

On October 27, 2009, we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales subject to potential reduction, subject to the terms of the agreement.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture the Company's ZolpiMist™ in the United States and Canada. ZolpiMist™ is our oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, ECR paid us $3,000,000 upon the execution of the agreement and will pay ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement.

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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.

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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.

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 nine patents which have been issued in the U.S. and 69 patents which have been issued outside of the U.S. Additionally, we have over 65 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.

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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

BECAUSE OUR COMMON STOCK IS LISTED ON THE OVER-THE-COUNTER BULLETIN BOARD, THE LIQUIDITY OF OUR COMMON STOCK MAY BE IMPAIRED.

On December 24, 2009, we announced that our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB. Our new ticker symbol on OTCBB is NVDL.OB. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009.

Because our common stock is listed on the OTCBB, the liquidity of the common stock is impaired, not only in the

number of shares that are bought and sold, but also through delays in the timing of transactions, and limited coverage by security analysts and the news media. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was traded on NYSE Amex LLC or another national securities exchange.

As of December 31, 2009, our net worth position was a deficit of $4,341,000 and as of December 31, 2008, our net worth position was a deficit of $2,741,000.

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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 24, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 42.1% 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 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 is currently listed for trading on the OTCBB under the symbol “NVDL.OB” and was previously traded on the NYSE Amex LLC from May 11, 2004 to December 23, 2009. During the twelve-month period ended

December 31, 2009, the closing price of our common stock has ranged from $0.12 to $0.52. 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, 2009, the average daily trading volume in our common stock was approximately 506,125 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.

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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 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.

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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 24, 2010, there were 89,283,000 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. As of March 24, 2010, we had outstanding stock options and warrants to purchase approximately 28.1 million shares of common stock, the exercise prices of which range between $0.17 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.

On July 16, 2009, we received approval from the NYSE Amex LLC to issue up to 12,000,000 shares over the next twelve (12) months. We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

The following table provides an overview of our stock options and corresponding plans, as of December 31, 2009:

Plan	Shares Authorized	Options Outstanding at December 31, 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	2,414,000	691,000	—
2006 Equity Incentive Plan	6,000,000	5,195,000	180,000	—
Non-Plan	n/a	581,000		—
Total	10,400,000	8,280, 000	871,000	

As of March 24, 2010, there are 2,414,000 and 5,195,000 options outstanding under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively. As a result, as of March 24, 2010, 691,000 and 180,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

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

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

See “Risk Factors - Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders” included herein. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain

additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

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

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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.

On July 16, 2009, we received approval from the NYSE Amex LLC to issue up to 12,000,000 shares over the next twelve (12) months. We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than

or equal to the stated floor price of $0.25 per share. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

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.

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

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

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

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

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

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

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

As of March 24, 2010, we have 89,283,000 shares of common stock issued and outstanding and approximately 28.1 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. 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 PRIVATE PLACEMENTS 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 2008 private placement were declared effective by the SEC on January 26, 2007, and July 16, 2008 and May 5, 2009, 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.

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

Our Board and management has broad discretion over the use of the net proceeds from our past financings, and will have broad discretion over the use of the net proceeds from any future financings. Stockholders may disagree with the judgment of the Board and management regarding the application of the proceeds. 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 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

As of February 1, 2010, our executive offices are located at 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807. We no longer maintain laboratory and warehousing space. Before February 1, 2010, our executive offices, laboratory, and warehousing space was located at 25 Minneakoning Road, Flemington, New Jersey, known as the Facility. The Facility, constituting approximately 31,800 square feet, was occupied under a 10-year lease, expiring in August 2013. During 2009, we only occupied a portion of our space in the Facility. During the years ended December 31, 2007, 2008 and 2009, we paid rent for the Facility of approximately $443,000, $453,000 and $257,000, respectively. We have contracted out manufacturing for our product candidates. The manufacture of our product candidates is subject to current Good Manufacturing Practices, or 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. RESERVED.

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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 Over-the-Counter Bulletin Board (OTCBB) under the ticker symbol "NVDL.OB" since December 24, 2009. It was previously listed on the NYSE Amex LLC 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 and OTCBB during the year ended December 31, 2008 and December 31, 2009.

	CLOSING SALE PRICES ($)	
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
	HIGH	LOW
YEAR ENDED DECEMBER 31, 2009		
First Quarter (January 1, 2009 through March 31, 2009)	0.40	0.20
Second Quarter (April 1, 2009 through June 30, 2009)	0.42	0.20
	0.32	0.23

Third Quarter (July 1, 2009 through September 30, 2009)		
Fourth Quarter (October 1, 2009 through December 31, 2009)	0.32	0.13

The last closing sales price of our common stock as reported on the OTCBB on March 24, 2010 was $0.24. As of March 24, 2010, there were approximately 63 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, 2009.

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	7,698,000	$ 0.69	871,000
Equity compensation plans not approved by security holders	581,000	2.38	—
Total	8,279,000	$ 0.81	871,000

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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, 2004 through December 31, 2009 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.

	7/04	7/05	7/06	12/06	12/07	12/08	12/09
NovaDel Pharma Inc.	$100.00	$73.10	$70.18	$95.91	$14.04	$18.71	$10.06
NYSE AMEX Composite	$100.00	$135.85	$166.48	$178.23	$212.06	$128.64	$174.52
Russell MicroCap	$100.00	$121.64	$125.03	$142.12	$130.75	$78.74	$100.38
RDG MicroCap Pharmaceutical	$100.00	$94.25	$84.72	$88.58	$71.34	$29.55	$32.30

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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, 2009, 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, 2009, 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. 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 the Balance Sheet data as of July 31, 2006 and July 31, 2005 are derived from our Financial Statements, which are not included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of future results of operations.

	Years Ended December 31,				Five Months Ended December 31,		Years Ended July	
Statement of Operations Data:	2009	2008	2007	2006 (unaudited)	2006	2005 (unaudited)	2006	20
Total Revenues	$422,000	$361,000	$469,000	$3,280,000	$2,067,000	$677,000	$1,890,000	$439,
Total Expenses	6,517,000	8,951,000	18,656,000	13,544,000	6,519,000	5,429,000	12,454,000	10,2
Loss from Operations	(6,095,000)	(8,590,000)	(18,187,000)	(10,264,000)	(4,452,000)	(4,752,000)	(10,564,000)	(9,7
Other, net	(385,000)	—	(66,000)	—	—	—	—	—
Interest Expense	2,160,000	1,868,000	—	—	—	—	—	—
Interest Income	6,000	137,000	632,000	337,000	180,000	67,000	224,000	87,0
Income Tax Benefit	(1,057,000)	(735,000)	(658,000)	(467,000)	(467,000)	(256,000)	(256,000)	(241
Net Loss	$(7,577,000)	$(9,586,000)	$(16,963,000)	$(9,460,000)	(3,805,000)	$(4,429,000)	$(10,084,000)	$(9,4
Basic and Diluted Loss Per Common Share	$(0.12)	$(0.16)	$(0.29)	$(0.20)	$(0.08)	$(0.11)	$(0.23)	$(0.2
Weighted Average Number of Shares of Common Stock Used in	61,345,671	59,592,000	59,497,000	46,732,000	49,522,000	40,619,000	43,000,000	34,8

Computation of Basic and Diluted Loss Per Share

	December 31,				July 31,	
BALANCE SHEET DATA:	2009	2008	2007	2006	2006	2005
Cash, cash equivalents, and short-term investments	$2,663,000	$4,328,000	$6,384,000	$20,276,000	$10,138,000	$8,223,000
Total Assets	4,453,000	7,316,000	10,363,000	24,316,000	14,822,000	13,028,000
Total Current Liabilities	4,588,000	5,563,000	4,211,000	3,146,000	2,200,000	2,405,000
Total Liabilities	8,794,000	10,057,000	6,189,000	5,718,000	4,777,000	5,079,000
Accumulated deficit	(82,766,000)	(74,829,000)	(65,243,000)	(48,280,000)	(44,475,000)	(34,391,000)
Total Stockholders' Equity (Deficiency)	$(4,341,000)	$(2,741,000)	$4,174,000	$18,598,000	$10,045,000	$7,949,000

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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 nine patents which have been issued in the U.S. and 69 patents which have been issued outside of the U.S. Additionally, we have over 65 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, 2009 of $82,766,000, as compared to $74,829,000 as of December 31, 2008. We have had negative cash flow from operating activities of $1,578,000 and $5,533,000 for the years ended December 31, 2009 and 2008, respectively. As of December 31, 2009, we had negative working capital of $495,000 as compared to working capital of $47,000 as of December 31, 2008, representing a net decrease in working capital of approximately $542,000.

Throughout 2009, our reduced clinical development activities were limited to expenditures required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products. We will seek to raise additional capital in 2010 to fund our operations and future development activities 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. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010. We will need additional financing thereafter until we achieve profitability.

Our audited financial statements for the fiscal year ended December 31, 2009 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 our

financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 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.

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As previously disclosed 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. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

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, 2009, and additionally through the date of filing of this Annual Report on Form 10-K, include the following:

Other

- Announced that Michael E. Spicer resigned as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. Our Board of Directors appointed Deni M. Zodda, Ph.D., 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.

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

- Announced the Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010. Mr. Ratoff will continue to serve as Interim Chief Financial Officer.

- Announced we executed a lease amendment modifying certain terms to the lease for the property in Flemington, New Jersey. The amendment converted the lease term to month to month commencing on July 1, 2009 with a provision that either party may terminate the lease upon thirty days written notice. We have released the lease escrow of $226,000 to the landlord in order to satisfy rent payments through June 30, 2009. This lease was terminated in December 2009.

- Effective February 1, 2010, we entered into a one (1) year lease agreement with Regus Management Group LLC for approximately 5,000 square feet of office space in Bridgewater, New Jersey.

- Announced that we entered into an agreement with Seaside 88, LP, or Seaside. Under the terms of the agreement and subject to the approval of the NYSE Amex LLC, Seaside has committed to purchase up to 13.0 million NovaDel common shares, in a series of closings every two weeks in the amount of 500,000 shares each for a total of up to 26 purchases. We had received approval from NYSE Amex LLC to issue up to 12.0 million shares over twelve (12) months. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we

mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

- Announced we entered into an agreement with Arthur W. Wood Company, Inc., or AWW, pursuant to which AWW agreed to assist us as a non-exclusive financial advisor for the purposes of seeking capital related to the Seaside offering, referred to herein as the Placement. In consideration of AWW's services, we agreed to pay AWW upon closing of a capital-raising transaction, a fee equal to three percent (3%) of the aggregate value of the proceeds paid or payable in the Placement.

- Announced we received a milestone payment of approximately $150,000 from Velcera, Inc., or "Velcera," relating to our License and Development Agreement with Velcera, dated June 22, 2004.

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- Announced we entered into a licensing agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales subject to potential reduction based upon the terms of the agreement.

- Announced we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. ZolpiMist™ is our oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the Agreement, we received $3,000,000 upon the execution of the agreement and ECR will pay us ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement.

- Announced that we notified NYSE Amex LLC ("Exchange") of our intent to voluntarily delist our common stock from the Exchange. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. Our common stock began trading on the OTCBB on December 24, 2009. Our new ticker symbol on OTCBB is NVDL.OB.

- Announced we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock as of December 31, 2009.

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

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

The successful development of our product candidates is highly uncertain. Estimates of the nature, timing and estimated expenses of the efforts necessary to complete the development of, and the period in which material net cash

inflows are expected to commence from any of our product candidates are subject to numerous risks and uncertainties, including:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- results of future clinical trials;
- the expense of clinical trials for additional indications;

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- 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	Mist Acquisition, LLC
Zolpimist™	zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals Company
Product Candidates				
Duromist™	sildenafil	Erectile Dysfunction	Preclinical development	-
Zensana™	ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.
NVD-201	sumatriptan	Migraines	Pilot Efficacy study complete	-
NVD-301	midazolam	Pre-Procedure Anxiety	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. On October 27, 2009, the Company entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC, or Mist, to manufacture and commercialize the NitroMist™ in the United States, Canada and Mexico. Under the terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement, and will pay us milestone payments totaling an additional $1,000,000 over the next twelve months if certain milestones are met and ongoing performance payments of up to seventeen percent (17%) of net sales. In addition, Mist will assume the activities and costs necessary for the completion of the product transfer to DPT Laboratories.

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Zolpimist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic for insomnia marketed by Sanofi-Aventis. Our oral spray formulation of zolpidem was approved for the short-term treatment of insomnia by the FDA in December 2008. In October 2009, we received a Notice of Allowance from the United States Patent and Trademark Office, or USPTO for claims which cover a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

Duromist™ (Sildenafil oral spray). Duromist 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 2010, with a development plan that would deliver a FDA approved product available for launch in the second quarter of 2012.

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 have notified Hana and Par that, under the terms of our agreement, they are required to return the product to us.

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 that their development activities will not be initiated until development is completed in the United States.

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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<0.011), and was comparable to the percentage who responded to the higher (100 mg) dose of the tablet formulation (42%). Significantly more patients had responded to all three doses of NVD-201 than to 50-mg Imigran® tablet by 90 minutes post-dosing (57% to 70.0% vs 32%; P<0.028) and all three oral spray doses were comparable to the 100-mg tablet. There were no treatment differences by 2 hours after dosing, when 68% to 77% of patients had responded irrespective of treatment.

Compared to 50-mg Imigran® tablet, at least one dose of NVD-201 also significantly increased percentage of patients who were pain free by 1 to 2 hours post-dosing, with the response ratio indicating significantly faster complete pain

relief for the 40-mg dose, and significantly more patients had complete pain relief without use of rescue medication after receiving any dose of NVD-201. In addition, after one or more doses of NVD-201, the percentage of patients who were asymptomatic was significantly increased, and the percentages who experienced nausea, photophobia, or phonophobia were significantly decreased. NVD-201 was comparable to the 100-mg tablet on all the above measures.

We believe NVD-201 may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, we believe NVD-201 may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due primarily to funding constraints, at the present time, in view of the other higher priorities associated with our current product pipeline, we do not anticipate further efforts on the project.

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We will continue to evaluate this program when sufficient additional funding becomes available.

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.

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.

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. On August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. This milestone payment resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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.

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REVENUE RECOGNITION – We receive revenue from license agreements and consulting services. 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. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured.

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 2008. We amortized approximately $25,000 to expense during the year ended December 31, 2009, upon which these costs are fully amortized.

WARRANTS ISSUED WITH CONVERTIBLE NOTES – The value of warrants and the intrinsic value of beneficial conversion rights arising from the issuance of convertible notes 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. We adopted Accounting Standards Codification, or ASC, 815-40-15 on January 1, 2009. ASC 815-40-15 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. The adoption of ASC 815-40-15 resulted in an adjustment to opening accumulated deficit in the amount of $360,000 to reclassify the fair value of certain outstanding warrants from stockholders' deficiency to liability. These warrants expired during the first quarter of 2009 and, as a result, the fair value of the warrant liability was reduced to zero and the Company recognized Other Income of $360,000 at the end of the reporting period.

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, 2009 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, 2009 was $324,000. We reviewed our long-lived property and equipment as of December 31, 2009, 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 – We calculate the fair value of stock-based compensation using the Black-Scholes method. Stock based compensation costs are recorded as earned for all unvested stock options outstanding. 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. We recorded share-based compensation expense of $326,000 for the year ended December 31, 2009, $771,000 for the year ended December 31, 2008, and $910,000 for the year ended December 31, 2007. We will continue to incur share-based compensation charges in future periods. As of December 31, 2009, unamortized share-based compensation expense of $880,000 remains to be recognized, which is comprised of $482,000 related to non-performance based stock options to be recognized over a weighted average period of 0.7 years, $104,000 related to restricted stock to be recognized over a weighted average period of 1.1 years, and $294,000 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.

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We used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants of all stock options in the respective periods:

	Years Ended	
	December 31, 2009	December 31, 2008
Expected volatility	85%	83%
Dividend yield	0%	0%
Expected term (years)	3.7	3.7
Risk-free interest rate	1.8%	2.3%

The above table represents the weighted-average assumptions for all stock options granted during the twelve months ended December 31, 2009 and 2008.

Expected volatility is based on historical volatility of our 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, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. We are utilizing a 5% forfeiture rate, which we believe 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.

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

NEW ACCOUNTING PRONOUNCEMENTS – In June 2009, the FASB issued FASB ASC 105, Generally Accepted Accounting Principles, or GAAP, which establishes the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. Pursuant to the provisions of FASB ASC 105, we have updated references to GAAP in our financial statements issued for the year ended December 31, 2009. The adoption of FASB ASC 105 did not impact our financial position or results of operations.

In April 2009, the FASB issued guidance now codified as FASB ASC Topic 825, Financial Instruments, which amends previous Topic 825 guidance to require disclosures about fair value of financial instruments in interim as well as annual financial statements. The adoption did not have a material impact on our results from operations or on our financial condition. Financial instruments include cash and cash equivalents and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

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RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2009 AND DECEMBER 31, 2008

License fees and milestone fees earned for the year ended December 31, 2009 were $422,000 as compared to $361,000 for the year ended December 31, 2008.

Research and development expenses for the year ended December 31, 2009 were $2,473,000 as compared to $3,878,000 for the year ended December 31, 2008. 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, 2009 and December 31, 2008.

	Fiscal Year Ended	
	December 31, 2009	December 31, 2008
NitroMist™	$ 592,000	$ 135,000
Zolpimist™	322,000	893,000
Sumatriptan	170,000	369,000
Zensana™	5,000	37,000
Tizanidine	-	41,000
Other research and development costs	210,000	242,000
Internal costs	1,174,000	2,161,000
Total research and development expenses	$ 2,473,000	$ 3,878,000

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

- NitroMist™, Zolpimist™, Sumatriptan and Tizanidine - 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. Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing throughout 2009, 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. 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, 2009 decreased primarily as a result of the following items:

- $457,000 increase in costs associated with our NitroMist™ product candidate primarily due to process validation, method transfer activities and lab supplies in the year ended December 31, 2009;

- $571,000 decrease in product development costs for our Zolpimist™ product candidate, as development efforts were substantially completed during 2007, including filing of an NDA. Costs for zolpidem in the year ended December 31, 2009 related to usage and lab supplies;

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- $199,000 decrease in product development costs for our Sumatriptan product candidate, due to delayed activity on this project;

- $987,000 decrease in internal costs is due to restructuring activities and substantially reduced efforts on R&D activities.

Consulting, selling, general and administrative expenses for the year ended December 31, 2009 were $4,044,000 as compared to $4,722,000 for the year ended December 31, 2008. 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 our employee-related costs and reduction in stock compensation expense due to decrease in headcount during the year.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2009 were $6,517,000, as compared to $8,951,000 for the year ended December 31, 2008.

Other income/(expense) for the year ended December 31, 2009 was $(385,000) which relates to the reversal of the warrant liability (upon expiration of the related warrants) initially recorded upon our adoption of ASC 815-40-15 in the amount of $360,000, offset with a loss on disposition of fixed assets in the amount of $745,000.

Interest expense for the year ended December 31, 2009 was $2,160,000 primarily related to the convertible notes that were issued during the year ended December 31, 2008.

Interest income for the year ended December 31, 2009 was $6,000 as compared to $137,000 for the year ended December 31, 2008, due to lower average cash and cash equivalent balances.

The resulting net loss for the year ended December 31, 2009 was $7,577,000 as compared to $9,586,000 for the year ended December 31, 2008.

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

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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.

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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. 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.

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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, 2009 of $82,766,000, as compared to $74,829,000 as of December 31, 2008. We have had negative cash flows from operating activities of $1,578,000 and $5,533,000 for the years ended December 31, 2009 and December 31, 2008, respectively. As of December 31, 2009, we had a working capital deficiency of $495,000 as compared to working capital of $47,000 as of December 31, 2008, representing a net decrease in working capital of approximately $542,000. Decrease is due to the conversion of convertible notes and associated liquidated damages and accrued interest of $3,700,000 to common stock, increase in other assets relating to receivable of $1,057,000 for net tax benefit offset by increase of deferred revenue of $4,000,000 and our loss for the year ended December 31, 2009 of $7,577,000.

Net cash used in operating activities was $1,578,000 for the year ended December 31, 2009, as compared to $5,533,000 for the year ended December 31, 2008. The $3,955,000 decrease in cash used is primarily due to the following:

- A reduction in net loss from $9,586,000 for the year ended December 31, 2008 to $7,577,000 for the year ended December 31, 2009, representing an improvement of $2,009,000.

- Non-cash expense of $1,360,000 upon debt conversion to common stock, $428,000 for the amortization of debt discount and deferred financing fees, and $746,000 on the loss on disposal of fixed assets, during the year ended December 31, 2009.

- $3,734,000 increase in deferred revenue for the year ended December 31, 2009 due to non-refundable license fees of $4,000,000 received during the fourth quarter 2009.

Net cash provided from financing activities was a decrease of $128,000 due to the following:

- $1,007,000 proceeds from the issuance of common stock during the year ended December 31, 2009.

- $1,000,000 partial payment of a convertible note made on April 29, 2009.

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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.

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 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 matured on November 30, 2008 and, in the Subsequent Closing, on April 17, 2009. On April 29, 2009, we remitted $1,000,000 to ProQuest against the $4,000,000 of convertible notes issued during 2008. On December 31, 2009, we entered into an amendment agreement with ProQuest to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock.

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 have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

On August 24, 2009, we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. This milestone payment resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

On October 27, 2009, we entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales subject to potential reduction based upon the terms of the Agreement. The Agreement contains customary termination provisions. In addition, the Agreement may be terminated by Mist for any reason upon written notice to us, which will be effective 180 days from the date of receipt of such notice, provided that Mist may not terminate until the second anniversary after the first commercial sale of NitroMist™ by Mist or its affiliates.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist™ in the United States, Canada and Mexico. Under the terms of the Agreement, we will receive a percentage of any income received by Mist under any sublicense agreement relating to NitroMist™.

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On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. ZolpiMist™ is our oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, ECR paid us $3,000,000 upon the execution of the agreement and ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement. A performance milestone will be due to us if net sales reach a certain level. We have an opportunity to co-promote zolpidem tartrate oral spray in the United States and Canada with ECR's consent, and retain commercialization rights for all other territories. ECR will assume responsibility for manufacturing the product for commercialization in the United States and Canada, including any activities required from the date of the agreement. The agreement contains customary termination provisions. In addition, the agreement may be terminated by ECR for any reason upon written notice to us, which will be effective 180 days from the date of receipt of such notice, provided that ECR may not terminate until the second anniversary after the first commercial sale of ZolpiMist™ by ECR or its affiliates.

We will seek to raise additional capital in 2010 to fund our operations and future development activities 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. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

Our audited financial statements for the fiscal year ended December 31, 2009 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 our financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 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.

As previously disclosed 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. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

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, 2009.

		Payments Due By Period			
	Total	<1 year	1-3 years	3-5 years	5 years +
Capital leases	$ 14,000	$ 10,000	$ 4,000	$ —	$ —
Operating leases	42,500	39,000	3,500	—	—
Employment agreements	627,000	627,000	—	—	—
Total contractual cash obligations	$ 683,500	$ 676,000	$ 7,500	$ —	$ —

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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, 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 officer and chief financial officer, 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, 2009. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2009, 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.

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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, 2009. 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, 2009, 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 2009, 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.

None.

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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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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, 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807. 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.

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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

ITEM 14. PRINCIPAL ACCOUNTANT 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 2010, which we intend to file within 120 days of the end of our fiscal year (December 31, 2009).

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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

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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 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.
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	Incorporated by reference to the Company's Registration Statement on

	Option Plan	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 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).

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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	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.31to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004.
10.11	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.
10.12	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.
10.13*	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.
10.14*	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.
10.15*	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.
10.16*		

	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.
10.17	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.
10.18*	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.
10.19*	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.
10.20*	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.
10.21*	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.

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10.22*	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.
10.23*	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.
10.24*	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.
10.25*	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.
10.26*	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.
10.27	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.
10.28	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 the SEC on November 14, 2007.
10.29	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.
10.30+	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.
10.31+		

	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.
10.32*	Separation, Consulting and General Release Agreement, effective as of April 30, 2009, by and between NovaDel Pharma Inc. and Deni M. Zodda	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on May 1, 2009.
10.33	Common Stock Purchase Agreement, by and between the Company and Seaside 88, LP, dated June 26, 2009	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 30, 2009.
10.34	Agreement, by and between the Company and Arthur W. Wood Company, dated June 15, 2009	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on July 20, 2009.
10.35+	License and Distribution Agreement, dated October 27, 2009, between NovaDel Pharma Inc. and Mist Acquisition, LLC	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 10, 2009.
10.36+	License and Distribution Agreement, dated November 12, 2009, between NovaDel Pharma Inc. and ECR Pharmaceuticals Company, Inc.	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 10, 2009.
10.37	Lease Agreement, dated as of December 7, 2009 and effective as of February 1, 2010, by and between Regus Management Group, LLC, as Landlord, and NovaDel Pharma Inc., as Tenant	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on January 14, 2010.

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10.38	Amendment Agreement, dated December 31, 2009, by and among NovaDel Pharma Inc., ProQuest Investment II, L.P., ProQuest Investment Advisors Fund II, 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 January 7, 2010.
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 Principal Executive Officer under Rule 13a-14(a)	Furnished herewith.
32.1	Certifications of the Principal Executive Officer and Principal 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.

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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 31, 2010 By: /s/ STEVEN B. RATOFF
Steven B. Ratoff
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 Steven B. Ratoff	Chairman, President, Chief Executive Officer, Interim Chief Financial Officer and Secretary (Principal Executive Officer)	March 31, 2010
/S/ MARK J. BARIC Mark J. Baric	Director	March 31, 2010
/S/ THOMAS E. BONNEY Thomas E. Bonney	Director	March 31, 2010
/S/ CHARLES NEMEROFF Charles Nemeroff	Director	March 31, 2010

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INDEX TO FINANCIAL STATEMENTS

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

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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, 2009 and 2008, and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008 and its results of operations and cash flows for each of the three years in the period ended December 31, 2009, 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 31, 2010

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NOVADEL PHARMA INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2009 AND 2008

ASSETS	December 31, 2009	December 31, 2008
Current Assets:		
Cash and cash equivalents	$2,663,000	$4,328,000
Assets held for sale	—	299,000
Deferred financing costs, net of accumulated amortization of $238,000 and $213,000, respectively	—	25,000
Prepaid expenses and other current assets	1,430,000	958,000
Total Current Assets	4,093,000	5,610,000
Property and equipment, net	324,000	1,447,000
Other assets	36,000	259,000
TOTAL ASSETS	$4,453,000	$7,316,000
LIABILITIES AND STOCKHOLDERS'DEFICIENCY		
Current Liabilities:		
Secured convertible notes payable, net of unamortized discount of zero and $403,000, respectively	$—	$3,597,000
Accounts payable	195,000	654,000
Accrued expenses and other current liabilities	117,000	924,000
Current portion of deferred revenue	4,266,000	266,000
Current portion of capital lease obligations	10,000	122,000
Total Current Liabilities	4,588,000	5,563,000
Non-current portion of deferred revenue	4,202,000	4,468,000
Non-current portion of capital lease obligations	4,000	26,000
Total Liabilities	8,794,000	10,057,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIENCY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		
Authorized 200,000,000 shares, Issued 88,343,457 and 60,692,260 at December 31, 2009 and 2008, respectively	89,000	60,000
Additional paid-in capital	78,342,000	72,034,000
Accumulated deficit	(82,766,000)	(74,829,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders' Deficiency	(4,341,000)	(2,741,000)

TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$4,453,000	$7,316,000

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2008 AND 2007

	Year Ended December 31,		
	2009	2008	2007
License Fees and Milestone Payments Earned	$ 422,000	$ 361,000	$ 469,000
Research and Development Expenses	2,473,000	3,878,000	11,940,000
Consulting, Selling, General and Administrative Expenses	4,044,000	4,722,000	6,716,000
Loss on Assets Held for Sale	—	351,000	
Total Expenses	6,517,000	8,951,000	18,656,000
Loss From Operations	(6,095,000)	(8,590,000)	(18,187,000)
Other, net	(385,000)	—	(66,000)
Interest Expense	(2,160,000)	(1,868,000)	—
Interest Income	6,000	137,000	632,000
Loss Before Income Tax Benefit	(8,634,000)	(10,321,000)	(17,621,000)
Income Tax Benefit	(1,057,000)	(735,000)	(658,000)
Net Loss	$ (7,577,000)	$ (9,586,000)	$ (16,963,000)
Basic and Diluted Loss Per Common Share	$ (0.12)	$ (0.16)	$ (0.29)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	61,346,000	59,592,000	59,497,000

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
FOR THE YEARS ENDED DECEMBER 31, 2009, 2008 AND 2007

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity (Deficiency)
	Shares	Amount					
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): Unrealized loss on investment in marketable equity security	—	—	—	—	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 beneficial conversion feature embedded in convertible notes	—	—	1,900,000	—	—	—	1,900,000
Net loss	—	—	—	(9,586,000)	—	—	(9,586,000)

BALANCE, December 31, 2008	60,692,260