NOVADEL PHARMA INC
Form 10-K
March 29, 2011

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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, 2010

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:

None

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

Common Stock, par value $0.001 per share
Title of class

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ¨ (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, 2010, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $12 million. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 21, 2011, the issuer had 113,523,192 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, 2010) are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART II

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FORWARD-LOOKING STATEMENTS

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 ability to develop products of the type the Company is developing (independently and through collaborative arrangements); the ability of third parties to commercialize the Company's products; the ability to complete clinical trials, including pilot pharmacokinetic feasibility studies; successful completion of preclinical studies; possible changes in the Company's financial condition; the progress of the Company's research and development; the ability to obtain adequate supplies of drug substance and drug product for clinical and preclinical studies, 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

In this report, all references to "NovaDel," "we," "our," "us" or the "Company" refer to NovaDel Pharma Inc., a Delaware corporation.

Item 1. Business.

Overview

NovaDel Pharma Inc. is a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy, safety, patient compliance, and patient convenience for a broad range of prescription medications. Our products and product candidates are as follows:

	Active Ingredient	Indications	Stage of Development	Partner
Products				
NitroMist®	Nitroglycerin	Angina Pectoris	Market	Akrimax Pharmaceuticals
ZolpimistTM	Zolpidem	Insomnia	Market	Hi-Tech Pharmacal
Product Candidates				
DuromistTM	Sildenafil	Erectile Dysfunction	Clinical development	—
ZensanaTM	Ondansetron	Nausea/Vomiting	Clinical development	Talon Therapeutics Par Pharmaceuticals BioAlliance Pharma Kwang Dong Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	—
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	—

Products

NitroMist®

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the United States Food and Drug Administration, or FDA, for acute relief of an attack of angina pectoris, or acute prophylaxis of angina pectoris, due to coronary artery disease. In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are

eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

ZolpimistTM

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

Product Candidates

DuromistTM

Duromist, our oral spray formulation of sildenafil, is being developed for the treatment of erectile dysfunction. Sildenafil is the active ingredient in Viagra®, a leading prescription medication for the treatment of erectile dysfunction, marketed by Pfizer. The patent for Viagra is expected to expire in the second quarter of 2012. We believe that an oral spray version of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

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The preclinical work has been completed, and a prototype formulation with satisfactory stability has been developed. In July 2010, we initiated a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist to Viagra. The trial was designed to assess the relative bioavailability and safety of one, two and three doses of 10 mg/0.12ml of Duromist, compared to that of the 25 mg Viagra tablet. The trial was a single-center, open-label, single-dose, randomized, four-period, four-treatment, crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24. All subjects were required to stay at the clinical site for at least 24 hours after each treatment period.

In October 2010, we announced positive data from this trial. The preliminary data demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure (AUC0-inf). The mean AUC0-inf for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean AUC0-inf for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet, which is about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses compared to the 25 mg Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (Cmax) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The Tmax (or time point at Cmax) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra tablet (1.10 and 1.04 hours, respectively). Duromist demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

In February 2011, we had a pre-IND meeting with the FDA. At that meeting we discussed the requirements for opening an IND, as well as the entire clinical and nonclinical development plan for a new drug application, or NDA, for Duromist. In 2011, we plan to open the IND, complete the required clinical and nonclinical work, and file a NDA. In order to do this we will need to secure additional funding or a development partner.

ZensanaTM

Zensana is our oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline, or GSK. In October 2004, we entered into an exclusive license and development agreement with Talon Therapeutics, Inc. (formerly Hana Biosciences, Inc.), or Talon, to develop and market Zensana in the U.S. and Canada. In July 2007, we entered into an amended and restated license and development agreement with Talon and a product development and commercialization sublicense agreement with Talon and Par Pharmaceutical, Inc., or Par, pursuant to which Talon 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. 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, and had ceased development of the product.

In January 2007, we entered into an exclusive license agreement with Kwang Dong Pharmaceuticals, or Kwang Dong, to develop and commercialize Zensana in South Korea. Under the terms of the agreement, we received an upfront fee of $100,000. We are eligible to receive additional milestone payments totaling $200,000, as well as royalty payments on net sales. Product development in South Korea is subject to the completion of product development in the U.S.

In May 2008, we entered into an exclusive license and supply agreement with BioAlliance Pharma SA, or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales. Product development in Europe is subject to the completion of

product development in the U.S.

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NVD-201

NVD-201 is our oral spray formulation of sumatriptan. Sumatriptan is the active ingredient in Imitrex®, a leading prescription medication for the treatment of migraine headache, marketed by GSK. We have completed a series of pilot pharmacokinetic clinical trials evaluating multiple doses of NVD-201 given to healthy adults. The results from these trials demonstrated that NVD-201 was well tolerated, achieved plasma concentrations in the therapeutic range, achieved a statistically significant increase in absorption rate when compared with Imitrex® tablets, and achieved up to a 50% increase in relative bioavailability in comparison with Imitrex® tablets. In September 2008, we announced the results from a pilot efficacy study for NVD-201. As previously announced, we believe this trial demonstrates that treatment with NVD-201 is safe and effective in relieving migraine headaches at a dose lower than that for sumatriptan tablets. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

NVD-301

NVD-301 is our oral spray formulation of midazolam. Midazolam is a leading prescription medication 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 in the relief of 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. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

Other Product Candidates

Our veterinary initiatives are being carried out by our partner, Velcera, Inc., or Velcera. In June 2004, we entered into an exclusive license and development agreement with Velcera. In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a canine pain management product. In August 2009 and March 2010, we received milestone payments from Velcera of $156,250 and $62,500, respectively. We are eligible to receive additional milestone payments, and royalty payments on sales.

In April 2003, we entered into an exclusive license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, for the development of propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. In July 2007, Manhattan announced its intention to pursue appropriate sub-licensing opportunities for this product candidate. In November 2010, the agreement was terminated.

Business Strategy

Our goal is to become a leading specialty pharmaceutical company that develops improved formulations of marketed prescription medications using our patented oral spray drug delivery technology. We believe that our technology has application to a broad range of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following criteria:

- Significant prescription sales already exist;
- Regulatory approval using the 505(b)(2) pathway is available; and
- Our patented oral spray drug delivery technology will enhance the performance of the pharmaceutical product, potentially addressing unmet patient needs.

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

Strategic Alliance, License and Other Commercial Agreements

We intend to secure marketing partners for our marketed products and development and commercialization partners for our product candidates. Typically, we secure development and commercialization partners after we have generated sufficient clinical data to demonstrate the effectiveness of our product candidates. We anticipate these strategic partners will provide us with upfront payments, milestone payments and royalties on product sales.

Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC

In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

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Hi-Tech Pharmacal Co., Inc., through its subsidiary ECR Pharmaceuticals Company, Inc.
In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales on branded products. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

Talon Therapeutics, Inc. (formerly Hana BioSciences, Inc.) and Par Pharmaceutical, Inc.
In October 2004, we entered into a license and development agreement pursuant to which we granted to Talon Therapeutics, Inc. (formerly Hana Biosciences, Inc.), or Talon, 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, Talon 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. We accounted for this premium as deferred revenue related to the license. In connection with the agreement, Talon issued to us $500,000 worth of common stock of Talon (73,121 shares based on a market value of $6.84 per share). The fair value of the common stock received from Talon was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, we entered into a sublicense agreement with Talon and Par Pharmaceutical, Inc., or Par, pursuant to which Talon granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana In connection therewith, Talon amended and restated their existing license and development agreement, as amended, with us relating to the development and commercialization of Zensana, to coordinate certain of the terms of the sublicense agreement. Under the terms of the sublicense agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. We retain our rights to Zensana outside of the United States and Canada.

In addition, under the terms of the amended and restated license agreement, Talon relinquished its right to pay reduced royalty rates to us until such time as Talon 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 Talon common stock that had been acquired by us in connection with execution of the original license agreement with Talon.

We may receive milestone payments and royalties over the term of the agreement.

Kwang Dong Pharmaceuticals
In January 2007, we entered into an exclusive license agreement with Kwang Dong Pharmaceuticals, or Kwang Dong, to develop and commercialize Zensana in South Korea. Under the terms of the agreement, we received an upfront fee of $100,000. We are eligible to receive additional milestone payments totaling $200,000, as well as royalty payments on net sales. Product development in South Korea is subject to the completion of product development in the U.S.

BioAlliance Pharma SA
In May 2008, we entered into a 19.5-year exclusive license and supply agreement with BioAlliance Pharma SA or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales. We anticipate collaborating with BioAlliance in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product.

Velcera, Inc.

In June 2004, we entered into a 20-year exclusive license agreement with Velcera, Inc., or Velcera, to develop and commercialize our patented oral spray drug delivery technology in animals. Under the terms of the agreement, we received an upfront payment of $1,500,000, as well as 529,500 shares of common stock in Velcera. The value of the shares of common stock was de minimis, and was valued at $0. We are eligible to receive additional milestone payments, as well as royalty payments on sales.

In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health to develop and commercialize a canine product. We received a milestone payment of $125,000 in connection with this agreement. In March 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause.

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In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a canine pain management product. In August 2009 and March 2010, we received milestone payments from Velcera of $156,250 and $62,500, respectively.

Manhattan Pharmaceuticals, Inc.
In April 2003, we entered into a 20-year exclusive license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, to develop propofol oral spray for the treatment of pre-procedural sedation. Under the terms of the agreement, we received a payment of $125,000 in June 2003, and a payment of $375,000 in November 2003. We are eligible to receive additional milestone payments, and royalty payments on sales. In July 2007, Manhattan announced that as part of a change in its strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate. In November 2010, the agreement was terminated.

Intellectual Property
Our policy is to pursue patents, pursue trademarks, maintain trade secrets and use other means to protect our technology, inventions and improvements that are commercially important to the development of our business.

We have applied for U.S. and foreign patent protection for our oral spray drug delivery technology, which is the primary focus of our development activities. Currently, we own nine patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we own 63 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 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.

Further, we own the registered trademark NITROMIST in the U.S. and Canada. In addition, we have applications for other trademarks pending around the world, which may or may not be granted.

Manufacturing and Clinical Supplies
We do not currently have in-house manufacturing capabilities. Our two approved products, NitroMist and Zolpimist, have been licensed to strategic partners, and these strategic partners are responsible for manufacturing. We rely on third party contract manufacturers to make the material used to support the development of our product candidates. We purchase the material used in our clinical trial activities from various companies and suppliers.

Sales and Marketing

We do not currently have sales or marketing capabilities. To date, we have chosen to license our approved products to strategic partners that have sales, marketing and distribution capabilities. In the future, we intend to pursue additional strategic alliances, as well as consider internal commercialization of our product candidates. Since we do not currently have the financial, and other, resources to undertake sales and marketing activities, if we are unable to enter into additional strategic alliances, we may not be able to successfully market our products or product candidates.

Customers and Distribution

We do not currently sell or distribute pharmaceutical products.

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Competition

We and our strategic partners face intense competition. We are in competition with organizations which are larger and or better capitalized than us. We will be competing against established pharmaceutical companies that currently market products which are equivalent or functionally similar to those we intend to market. Prices of pharmaceutical 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.

Government Regulation

Pharmaceutical Regulation

The Food and Drug Administration, or FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution and export of pharmaceutical products, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these areas. We may be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied or marketed abroad. The approval process outside the U.S. varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Regulation in the United States

New Drug Applications

The FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act or FDCA. The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our products will ever obtain approval. The FDA approval process for new drugs generally includes the following to enable the FDA to evaluate the product’s safety and effectiveness:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices regulations to assess potential safety and effectiveness;
- submission and approval of an Investigational New Drug Application, or IND, including results of pre-clinical studies, manufacturing information, and protocols for clinical studies, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of Institutional Review Boards, or IRBs, to administer the product candidates to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
-

development of manufacturing processes that conform to FDA current Good Manufacturing Practices, or cGMPs, as confirmed by FDA inspection;

- submission of results from pre-clinical and clinical studies, and chemistry, manufacturing and controls, or CMC, information on the product to the FDA in a New Drug Approval Application, or NDA; and
- FDA review and approval of a NDA prior to any commercial sale or shipment of a product.

We cannot commence any clinical trials for our product candidates in the U. S. before we file an IND. Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

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Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator. Each clinical trial must be reviewed and approved by an IRB, which will consider, among other things, ethical factors, and safety of human subjects. Also, clinical trials must be performed according to good clinical practices, which are enumerated in FDA regulations and guidance documents. The FDA or the IRB may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

Clinical trials typically are conducted in sequential phases that may overlap: Phases 1, 2, 3 and 4.

In Phase 1 clinical trials, a drug is introduced into a small number of healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.

In Phase 2 clinical trials, a drug is usually tested on a limited number (generally up to several hundred) of subjects with the disease or medical condition for which the new drug is intended to be used, in order to determine dosage tolerance and optimal effective dose. Phase 2 studies evaluate the efficacy of the drug for specific, targeted indications, identify possible adverse effects and safety risks, and confirm the parameters to be used in expanded testing in Phase 3.

In Phase 3 clinical trials, a drug is usually tested on a larger number of subjects (up to several thousand), in an expanded patient population and at multiple clinical sites to demonstrate substantial evidence of clinical efficacy and safety to secure marketing approval.

In Phase 4 clinical trials or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. Post-approval studies may be a requirement of NDA approval, or as part of a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of the product outweigh the risks. Additionally, FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. When an accelerated approval is based upon a surrogate endpoint, postmarketing studies are ordinarily required to verify and describe the drug's clinical benefit and to resolve remaining uncertainty as to the relation of the surrogate endpoint upon which approval was based to clinical benefit, or the observed clinical benefit to ultimate outcome. Failure to promptly conduct Phase 4 clinical trials could result in FDA withdrawing approval granted under accelerated approval regulations.

We cannot assure you that we will successfully complete clinical testing of our product candidates within any specific time period, if at all.

The NDA is the request to market and commercially distribute the product, and must contain results of laboratory testing and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition to demonstrate that the product is safe and effective for its intended use. The facilities, procedures and operations for any of our contract manufacturers must be determined to be adequate by the FDA before product approval. Manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications and other FDA regulations before and after a NDA has been approved. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approval of NDAs or other product applications if deficiencies are found at the facility. Vendors that may supply us with finished products or components used to manufacture, package and label products are also subject to similar regulations and periodic inspections.

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2010 for the fiscal year 2011, the user fee for an application requiring clinical data, such as an NDA, is $1,542,000. The FDA adjusts the user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs ($86,520), and an annual establishment fee ($497,200) on facilities used to manufacture prescription drugs. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees.

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After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, new indications for use, or other areas will require submission of an NDA Supplement to FDA for review and approval.

Failure to comply with FDA and other governmental regulations may result in an enforcement action by FDA, including Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties and fines.

Section 505(b)(2) New Drug Applications

An NDA is submitted pursuant to Section 505(b)(1) or 505(b)(2) of the FDCA. A 505(b)(1) application requires full reports of safety and effectiveness. A 505(b)(2) application relies on information for which the applicant does not have a right of reference. For example, the applicant may rely, in part, on the safety and efficacy data of a product approved by FDA, or published medical literature, in support of its application. A 505(b)(2) application may provide an abbreviated pathway to FDA approval for new or improved formulations or new uses of previously approved products. 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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. 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. Thus, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

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

Regulation Outside the United States

If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. There is no assurance that any future FDA approval of any of our clinical trials or drugs will result in similar foreign approvals or vice versa.

Additional Regulation

Third-Party Reimbursement

In the United States, physicians, hospitals and other healthcare providers, including pharmacies, that purchase pharmaceutical products generally rely on third-party payors, principally private health insurance plans, pharmacy benefits managers, Medicare and, to a lesser extent, Medicaid, to reimburse all or part of the cost of the product and when used in an institutional setting or a physician’s office, the procedure for which the product is being used. Even if a product is approved for marketing by the FDA, there is no assurance that third-party payors will cover the product, or fully reimburse the cost of the product if covered and related medical procedures. If they do not, purchasers of the drug would incur a financial loss on purchase and administration or dispensing of the drug, and our ability to market any such drug would be materially and adversely impacted.

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Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the United States, the lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit their widespread use and lower potential product revenues.

Fraud and Abuse Laws

Federal and state anti-kickback and anti-fraud and abuse laws, as well as the federal Civil False Claims Act may apply to certain drug and device research and marketing practices. The Civil False Claims Act prohibits knowingly presenting or causing to be presented a false, fictitious or fraudulent claim for payment to the United States. Actions under the Civil False Claims Act may be brought by the Attorney General or by a private individual acting as an informer or whistleblower in the name of the government. Violations of the Civil False Claims Act can result in significant monetary penalties and other potential sanctions. A judgment involving a finding of liability under the False Claims Act could also trigger the threat of permissive exclusion of the entity by the Department of Health and Human Services or the Office of Inspector General. The federal government is using the Civil False Claims Act, and the threat of significant liability, in its investigations of healthcare providers, suppliers and drug and device manufacturers throughout the country for a wide variety of drug and device marketing and research practices, and has obtained multi-million dollar settlements. The federal government may continue to devote substantial resources toward investigating healthcare providers', suppliers' and drug and device manufacturers' compliance with the Anti-Kickback Law, Civil False Claims Act and other fraud and abuse laws. We may have to expend significant financial resources and management attention if we ever become the focus of such an investigation, even if no illegal conduct occurred.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, requires that covered entities, including many healthcare care providers, health plans and healthcare clearinghouses, use certain standard electronic transactions and safeguard the privacy and security of protected health information. The Department of Health and Human Services has promulgated regulations implementing these HIPAA standards in the United States. Additional regulations are to be promulgated to implement amendments to the HIPAA privacy and security standards pursuant to the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, which is part of the American Recovery and Reinvestment Act of 2009.

Employees

As of March 1, 2011, we had 4 employees, all of whom were full-time employees.

Company Information

We were incorporated in the state of Delaware in 1982. Our corporate offices are located at 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey, 08807. Our telephone number is (908) 203-4640. Our website address is www.novadel.com. Information contained on, or accessible through, our website is not part of this report or our other filings with the Securities and Exchange Commission, or SEC. We make available free of charge on our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, as soon as reasonably practicable after we electronically file such reports with the SEC. Our SEC filings are also available to the public from the SEC's website at www.sec.gov.

Item 1A. Risk Factors.

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, 2010, 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 2010 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.

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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.

Since 2007, we significantly reduced expenditures on our approved products and our product candidate pipeline. During 2010, we utilized capital primarily to maintain the FDA approvals for NitroMist and Zolpimist, our two approved products, and to progress development for our product candidate Duromist. In 2010, we initiated and completed a pilot PK study of Duromist. During 2011, we intend to use additional capital to complete the clinical trials for Duromist and file a New Drug Application for product approval. 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.

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.

During 2010, we recorded net proceeds of $1,514,000 from public and private offerings of our securities. We are seeking to raise additional capital in 2011 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.

As of December 31, 2010, we had $900,000 in cash and cash equivalents, and $744,000 in receivables. We collected the entire $744,000 of receivables in January and February 2011. In February 2011, we sold 1,667 shares of our preferred stock for gross proceeds of approximately $1.6 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through June 30, 2011.

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.

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Since 2007, we significantly reduced expenditures on our approved products and our product candidate pipeline. During 2010, we utilized capital primarily to maintain the FDA approvals for NitroMist and Zolpimist, our two approved products, and to progress development for our product candidate Duromist. In 2010, we initiated and completed a pilot PK study of Duromist. During 2011, we intend to use additional capital to complete the clinical trials for Duromist and file a New Drug Application for product approval. 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. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Product revenues for products which we license out are dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of Akrimax relating to NitroMist and HiTech Pharmacal relating to Zolpimist.

We are a 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 commercially launched these products in January 2011. We cannot be certain as to when to anticipate commercializing and marketing any of our other 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.

We had an accumulated deficit as of December 31, 2010 of approximately $85,432,000. We incurred losses in each of our last three fiscal years, including net losses of approximately $2,666,000 for the year ended December 31, 2010, $7,577,000 for the year ended December 31, 2009 and $9,586,000 for the year ended December 31, 2008. Additionally, we have reported negative cash flows from operations of $3,280,000 for the year ended December 31, 2010, $1,578,000 for the year ended December 31, 2009 and $5,533,000 for the year ended December 31, 2008. 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 administrative costs associated with operating as a SEC registrant. We 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 receive product revenue from the sale of products and achieve profitability is dependent on a number of factors, including our ability to complete the development of our product candidates, obtain the required regulatory approvals and the successful commercialization of our product candidates by commercial partners.

The uncertainty created by current economic conditions and possible terrorist attacks and military responses thereto could have a material adverse effect on our ability to sell our products, and to secure additional 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 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.

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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.

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, such as our Duromist product candidate, 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 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 Kwang Dong, Mist, ECR, BioAlliance, Par, Velcera and Talon, 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 current 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.

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 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.

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.

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

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

Limited product liability insurance coverage may affect our business.

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

Extensive government regulation may affect our business.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal U.S. regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product’s safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have

been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

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

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

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects. The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist 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 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.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our current and future products profitably.

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our current and future products profitably.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act or PPACA, which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. Effective January 1, 2010, the new law increases the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or “donut hole.” The law also revises the definition of “average manufacturer price” for reporting purposes (effective October 1, 2011), which could increase the amount of our Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2010). Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

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The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional change could be made to governmental healthcare programs that could significantly impact the success of our current and future products, and we could be adversely affected by current and future health care reforms.

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 agreement, 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.

We have entered into strategic license agreements with: (i) Talon, for the development and marketing rights in the U.S. and Canada which were subsequently sublicensed to Par for our ondansetron oral spray Zensana, (ii) Velcera, in connection with veterinary applications for currently marketed veterinary drugs, (iii) BioAlliance Pharma SA, for the European rights for ondansetron oral spray Zensana, (iv) Mist Acquisition, LLC, for the manufacturing and commercialization rights in the United States, Canada and Mexico for our lingual spray version of nitroglycerine, NitroMist, (v) ECR Pharmaceuticals Company, for the manufacturing and commercialization rights in the United States and Canada for our oral spray formulation of zolpidem tartrate, Zolpimist, (vi) Kwang Dong Pharmaceuticals, for the South Korean rights for ondansetron oral spray Zensana.

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize proposed products. For example, in November 2008, Par announced that it had completed bioequivalence studies on Zensana with mixed results and, as a result, it had ceased development of the product. Since such time, we have had numerous meetings and discussions with both Par and Talon regarding the development of Zensana. We cannot assure you that Par or Talon will perform under our license agreements.

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.

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

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

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

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

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. 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.”

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Intellectual property rights of third parties could limit our ability to market our products.

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

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

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

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

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

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

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

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

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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.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on our stock price.

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

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

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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 requires the commitment of 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.

There are certain interlocking relationships and potential conflicts of interest.

Mr. Steven B. Ratoff, our Chairman, President, and Chief Executive Officer, has a relationship, both with us as well as with certain of our affiliates, which creates the potential for a perceived conflict of interest. As of December 31, 2010, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., collectively referred to herein as ProQuest, directly and indirectly, beneficially owns approximately 42% of our outstanding common stock (assuming full exercise of the warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. Mr. Ratoff has served as a venture partner with ProQuest since December 2004. However, he has no authority for investment decisions by ProQuest.

As a result of this and other relationships, the potential for perceived conflicts of interest exists. In addition, in the event that we become involved in stockholder litigation regarding these potential conflicts, we might be required to devote significant resources and management time defending the company from these claims, which could adversely affect our results of operations.

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.

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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. Our certificate of incorporation allows us to issue shares of preferred stock without any vote or further action by our common stockholders. For example, on February 11, 2011, we authorized 1,667 shares of Series A Preferred Stock in connection with our public offering of Series A Preferred Stock and accompanying warrants. Our Board has the authority to fix and determine the relative rights and preferences of such 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.

Limitation on director and 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.

Risk Related to Our Common Stock

Because our common stock is quoted on the Over-the-Counter Bulletin Board, the liquidity of our common stock may be impaired.

Because our common stock is quoted on the Over-the-Counter Bulletin Board, or 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 listed on NYSE Amex LLC or another national securities exchange.

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 December 31, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 47% 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.

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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.

During the year ended December 31, 2010, the closing price of our common stock has ranged from $0.14 to $0.29. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Our relatively low volume and low number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

Because the average daily trading volume of our common stock is low, the ability to sell our shares in the secondary trading market may be limited.

Because the average daily trading volume of our common stock 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.

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.

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Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the "penny stock" rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

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

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

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

Additional authorized shares of our common stock and preferred stock available for issuance may result in dilution or 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 common stockholders. As of December 31, 2010, there were 98,681,029 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 December 31, 2010, we had outstanding stock options and warrants to purchase approximately 29.9 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. In addition, as of December 31, 2010, 470,000 and 10,281,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

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

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. 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, on February 11, 2011, we authorized 1,667 shares of Series A Preferred Stock in connection with our public offering of Series A Preferred Stock and accompanying warrants. As of the closing of this transaction, we did

not have a sufficient number of shares of our common stock authorized to permit the full exercise of the accompanying warrants. As a result, we have agreed to hold a stockholders' meeting no later than July 31, 2011 to approve an increase in the authorized shares of our common stock to permit the full exercise of such warrants.

While we have no present plans to issue any additional shares of preferred stock, our Board has the authority, without stockholder approval (other than approval by the holders of the Series A Preferred Stock), 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.

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.

Sales of large quantities of our common stock by our stockholders, including those shares issued in connection with private placement transactions, could reduce the price of our common stock.

Since May 2005, we have entered into private placements and registered direct offerings whereby we sell large quantities of our common stock to investors. For example, on March 31, 2010, we sold 9,100,001 shares of our common stock at a price of $0.165 per share to certain investors in a registered direct offering. The investors also received warrants to purchase 7,583,335 shares of common stock with an exercise price of $0.25 per share

These holders of the shares may sell such shares, if such shares are registered or pursuant to an exemption from registration, at any price and at any time, as determined by such holders in their sole discretion without limitation. Any sales of large quantities of our common stock could reduce the price of our common stock. 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.

We cannot assure you of the prices at which our common stock will trade in the future, and such prices 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.

As of December 31, 2010, we have 98,681,029 shares of common stock issued and outstanding and approximately 29.9 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. For example, we have agreed to hold a stockholders' meeting no later than July 31, 2011 to approve an increase in the authorized shares of our common stock to permit the full exercise of certain of the warrants issued in our public

offering of Series A Preferred Stock and accompanying warrants in February 2011. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

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.

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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 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of February 1, 2010, we lease four offices in Bridgewater, New Jersey, pursuant to a lease agreement that expires in January 2012. We believe that our current facilities are adequate for our needs through January 2012.

Before February 1, 2010, we leased approximately 31,800 square feet of laboratory, warehouse, and office space in Flemington, NJ. We no longer lease that facility.

Item 3. Legal Proceedings.

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

Item 4. (Removed and Reserved).

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

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, 2009 and December 31, 2010.

	Closing Sale Prices ($)	
	High	Low
Year Ended December 31, 2009		
First Quarter	0.40	0.20
Second Quarter	0.42	0.20
Third Quarter	0.32	0.23
Fourth Quarter	0.32	0.13
Year Ended December 31, 2010		
First Quarter	0.16	0.28
Second Quarter	0.18	0.23
Third Quarter	0.15	0.20
Fourth Quarter	0.16	0.25

Holders

The number of record holders of our common stock as of March 24, 2011 was approximately 62. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividend Policy

We have never paid dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Equity Compensation Plans

Information regarding our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated by reference herein.

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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, 2006 through December 31, 2010 of an initial investment of $100 invested in (a) NovaDel Pharma Inc.'s common stock, (b) the Total Return Index for the Russell Micro Cap Index 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.

	7/06	12/06	12/07	12/08	12/09	12/10
NovaDel Pharma Inc.	100.00	136.67	20.00	26.67	14.33	15.42
Russell MicroCap	100.00	113.67	104.58	62.98	80.28	103.48
RDG MicroCap Pharmaceutical	100.00	106.23	95.16	42.32	40.50	36.16

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Item 6. Selected Financial Data

The following Selected Financial Data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7, and the financial statements and the notes to those statements beginning on page F-1 of this Annual Report on Form 10-K. The data set forth below for the year ended December 31, 2006 is unaudited, and there were no seasonal or other significant factors which affect comparability. The data set forth below with respect to our Balance Sheet data as of July 31, 2006 is derived from our Financial Statements, which are not included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,					Five Months Ended December 31,	Year Ended July 31,
Statement of Operations Data:	2010	2009	2008	2007	2006	2006	2006
	(In thousands, except per share amounts)						
					(unaudited)		
Total revenue	$2,826	$422	$361	$469	$3,280	$2,067	$1,890
Total expense	5,794	6,517	8,951	18,656	13,544	6,519	12,454
Loss from operations	(2,968)	(6,095)	(8,590)	(18,187)	(10,264)	(4,452)	(10,564)
Other income (expense), net	302	(385)	—	(66)	—	—	—
Interest expense	1	2,160	1,868	—	—	—	—
Interest income	1	6	137	632	337	180	224
Income tax benefit	—	(1,057)	(735)	(658)	(467)	(467)	(256)
Net loss	$(2,666)	$(7,577)	$(9,586)	$(16,963)	$(9,460)	$(3,805)	$(10,084)
Basic and diluted loss per common share	$(0.03)	$(0.12)	$(0.16)	$(0.29)	$(0.20)	$(0.08)	$(0.23)
Weighted average common shares outstanding – basic and diluted	95,618	61,346	59,592	59,497	46,732	49,522	43,000

	December 31,					July 31,
Balance Sheet Data:	2010	2009	2008	2007	2006	2006
	(In thousands)					
Cash, cash equivalents,	$ 900	$2,663	$4,328	$6,384	$20,276	$10,138

and short-term investments						
Total assets	2,218	4,453	7,316	10,363	24,316	14,822
Total current liabilities	4,372	4,588	5,563	4,211	3,146	2,200
Total liabilities	8,061	8,794	10,057	6,189	5,718	4,777
Accumulated deficit	(85,432)	(82,766)	(74,829)	(65,243)	(48,280)	(44,475)
Total stockholders' equity (deficiency)	$(5,843)	$(4,341)	$(2,741)	$4,174	$18,598	$10,045

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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.

Overview

Company Overview

NovaDel Pharma Inc. is a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy, safety, patient compliance, and patient convenience for a broad range of prescription medications. Our products and product candidates are as follows:

	Active Ingredient	Indications	Stage of Development	Partner
Products				
NitroMist®	Nitroglycerin	Angina Pectoris	Market	Akrimax Pharmaceuticals
ZolpimistTM	Zolpidem	Insomnia	Market	Hi-Tech Pharmacal
Product Candidates				
DuromistTM	Sildenafil	Erectile Dysfunction	Clinical development	—
ZensanaTM	Ondansetron	Nausea/Vomiting	Clinical development	Talon Therapeutics Par Pharmaceuticals BioAlliance Pharma Kwang Dong Pharma.
NVD-201	Sumatriptan	Migraine headache	Clinical development	—
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	—

NitroMist®

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the United States Food and Drug Administration, or FDA, for acute relief of an attack of angina pectoris, or acute prophylaxis of angina pectoris, due to coronary artery disease. In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a

milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

ZolpimistTM

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

DuromistTM

Duromist, our oral spray formulation of sildenafil, is being developed for the treatment of erectile dysfunction. Sildenafil is the active ingredient in Viagra®, a leading prescription medication for the treatment of erectile dysfunction, marketed by Pfizer. The patent for Viagra is expected to expire in the second quarter of 2012. We believe that an oral spray version of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

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The preclinical work has been completed, and a prototype formulation with satisfactory stability has been developed. In July 2010, we initiated a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist to Viagra. The trial was designed to assess the relative bioavailability and safety of one, two and three doses of 10 mg/0.12ml of Duromist, compared to that of the 25 mg Viagra tablet. The trial was a single-center, open-label, single-dose, randomized, four-period, four-treatment, crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24. All subjects were required to stay at the clinical site for at least 24 hours after each treatment period.

In October 2010, we announced positive data from this trial. The preliminary data demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure (AUC0-inf). The mean AUC0-inf for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean AUC0-inf for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet, which is about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses compared to the 25 mg Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (Cmax) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The Tmax (or time point at Cmax) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra tablet (1.10 and 1.04 hours, respectively). Duromist demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

In February 2011, we had a pre-IND meeting with the FDA. At that meeting we discussed the requirements for opening an IND, as well as the entire clinical and nonclinical development plan for a new drug application, or NDA, for Duromist. In 2011, we plan to open the IND, complete the required clinical and nonclinical work, and file a NDA. In order to do this we will need to secure additional funding or a development partner.

ZensanaTM

Zensana is our oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline, or GSK. In October 2004, we entered into an exclusive license and development agreement with Talon Therapeutics, Inc. (formerly Hana Biosciences, Inc.), or Talon, to develop and market Zensana in the U.S. and Canada. In July 2007, we entered into an amended and restated license and development agreement with Talon and a product development and commercialization sublicense agreement with Talon and Par Pharmaceutical, Inc., or Par, pursuant to which Talon 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. 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, and had ceased development of the product.

In January 2007, we entered into an exclusive license agreement with Kwang Dong Pharmaceuticals, or Kwang Dong, to develop and commercialize Zensana in South Korea. Under the terms of the agreement, we received an upfront fee of $100,000. We are eligible to receive additional milestone payments totaling $200,000, as well as royalty payments on net sales. Product development in South Korea is subject to the completion of product development in the U.S.

In May 2008, we entered into an exclusive license and supply agreement with BioAlliance Pharma SA, or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales. Product development in Europe is subject to the completion of product development in the U.S.

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NVD-201

NVD-201 is our oral spray formulation of sumatriptan. Sumatriptan is the active ingredient in Imitrex®, a leading prescription medication for the treatment of migraine headache, marketed by GSK. We have completed a series of pilot pharmacokinetic clinical trials evaluating multiple doses of NVD-201 given to healthy adults. The results from these trials demonstrated that NVD-201 was well tolerated, achieved plasma concentrations in the therapeutic range, achieved a statistically significant increase in absorption rate when compared with Imitrex® tablets, and achieved up to a 50% increase in relative bioavailability in comparison with Imitrex® tablets. In September 2008, we announced the results from a pilot efficacy study for NVD-201. As previously announced, we believe this trial demonstrates that treatment with NVD-201 is safe and effective in relieving migraine headaches at a dose lower than that for sumatriptan tablets. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

NVD-301

NVD-301 is our oral spray formulation of midazolam. Midazolam is a leading prescription medication 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 in the relief of 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. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

Other Product Candidates

Our veterinary initiatives are being carried out by our partner, Velcera, Inc., or Velcera. In June 2004, we entered into an exclusive license and development agreement with Velcera. In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a canine pain management product. In August 2009 and March 2010, we received milestone payments from Velcera of $156,250 and $62,500, respectively. We are eligible to receive additional milestone payments, and royalty payments on sales.

In April 2003, we entered into an exclusive license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, for the development of propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. In July 2007, Manhattan announced its intention to pursue appropriate sub-licensing opportunities for this product candidate. In November 2010, the agreement was terminated.

Going Concern and Management’s Plan

Our independent registered public accounting firm has included an explanatory paragraph in their report on our 2010 financial statements related to the uncertainty and substantial doubt of our ability to continue as a going concern.

We have incurred net losses of $2.7 million, $7.6 million, and $9.6 million for the years ended December 31, 2010, 2009 and 2008, respectively. Since inception, and through December 31, 2010, we have accumulated deficit of $85.4 million.

As of December 31, 2010, we had $900,000 in cash and cash equivalents, and $744,000 in receivables. We collected the entire $744,000 of receivables in January and February 2011. In February 2011, we sold 1,667 shares of our preferred stock for gross proceeds of approximately $1.6 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through June 30, 2011. These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Results of Operations

Comparison of the Year ended December 31, 2010 and 2009
License fees, milestone fees and other revenue earned for the year ended December 31, 2010 were $2,826,000 as compared to $422,000 for the year ended December 31, 2009. The increase was primarily due to license fees and milestone fees of $2,000,000 that were earned by us achieving contractual milestones associated with the launch of NitroMist. We were also awarded a grant for $244,000 under the Federal Qualifying Therapeutic Discovery Project program.

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Total operating expenses decreased by $723,000 or 11% from $6,517,000 in 2009 to $5,794,000 in 2010.

Research and development expenses increased by $313,000, or 13%, from $2,473,000 in 2009 to $2,786,000 in 2010. Research and development costs consist primarily of fees paid to contract research organizations, manufacturing costs for our product candidates, contractor and consulting fees, salaries and benefits, and allocated facility and administrative costs. Research and development expenses increased primarily as a result of a $1,838,000 increase in costs associated with the development of Duromist, our sole development focus in 2010. The costs included all activities related to the planning and execution of our non-IND pilot PK clinical trial. The increase in cost for the Duromist program was partially offset by a decrease in costs for all other development programs, as well as a decline in personnel costs and facility costs.

General and administrative expenses decreased by $1,036,000, or 26%, from $4,044,000 in 2009 to $3,008,000 in 2010. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and administrative personnel, professional fees, facility costs, and other corporate expenses. The decrease is primarily attributable to reduced personnel costs, due to a decrease in headcount, and reduced facility costs, due to the relocation of our offices.

Other income from a valuation adjustment of a derivative liability was $302,000 in 2010. The derivative liability is related to warrants issued in conjunction with our common stock offering on March 31, 2010. The income was due to a gain resulting from the decline in the fair value of the derivative liability at December 31, 2010. The decline in the fair value of the derivative liability was due to the decrease in the price of our common stock, as well as the expiration of certain warrants on September 30, 2010. Other income from a valuation adjustment of a derivative liability was $360,000 in 2009. This derivative liability was related to warrants issued in conjunction with a convertible notes offering in 2008. The income was recorded upon the expiration of warrants.

In 2009 we incurred a loss on disposition of fixed assets in the amount of $745,000 related to the relocation of facilities. There was no such activity in 2010.

Interest expense decreased by $2,159,000, or 99%, from $2,160,000 in 2009 to $1,000 in 2010. The interest was incurred on our convertible notes. This decrease in interest expense reflects the conversion of the convertible notes to common stock in 2009.

The resulting net loss for the year ended December 31, 2010 was $2,666,000 as compared to $7,577,000 for the year ended December 31, 2009.

Comparison of the Year 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.

Total operating expenses decreased by $2,434,000, or 27%, from $8,951,000 in 2008 to $6,517,000 in 2009.

Research and development expenses decreased by $1,405,000, or 36%, from $3,878,000 in 2008 to $2,473,000 in 2009. Research and development costs consisted primarily of salaries and benefits, contractor and consulting fees, drug supplies for preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Research and development expenses in the year ended December 31, 2009 decreased primarily as a result of a $987,000 decrease in internal costs due to restructuring activities and substantially reduced development activities, a $571,000 decrease in product development costs for our Zolpimist™ product candidate, as development efforts were substantially completed during 2007, and a $199,000 decrease in product development costs

for our Sumatriptan product candidate, due to delayed activity on this project. These decreases were offset in part by a $457,000 increase in costs associated with NitroMist, primarily process validation, method transfer activities and lab supplies expenses.

General and administrative expenses decreased by $678,000, or 14% from $4,722,000 in 2008 to $4,044,000 in 2009. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and administrative personnel, professional fees, facility costs, and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to a decrease in our employee-related costs and a reduction in stock compensation expense due to a decrease in headcount during the year.

Other income (expense) for the year ended December 31, 2009 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, and the loss on disposition of fixed assets in the amount of $745,000.

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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.

Liquidity and Capital Resources

From our inception, our principal sources of capital have been revenue from our partnership agreements, consulting revenue, 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, 2010 of $85,432,000, as compared to $82,766,000 as of December 31, 2009. We have had negative cash flows from operating activities of $3,280,000 and $1,578,000 for the years ended December 31, 2010 and December 31, 2009, respectively. As of December 31, 2010, we had a working capital deficiency of $2,382,000 as compared to working capital deficiency of $495,000 as of December 31, 2009, representing a net decrease in working capital of approximately $1,887,000. The decrease in working capital was primarily attributable to our net loss of for the year ended December 31, 2010 of $2,666,000 offset in part by $1,514,000 in net proceeds from the issuance of common stock through private placements in 2010.

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 these sources of capital in transactions similar to those 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.

During the periods covered by our financial statements, we have financed our operations primarily through the following transactions:

- In March 2010, we completed a registered direct offering of 9,100,001 shares of our common stock, at a price of $0.165 per share, for net proceeds of $1,323,000. The investors received five-year warrants to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. The exercise price of these warrants are subject to adjustment as provided by such warrants.

- In July 2009, we entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP would 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 was greater than or equal to the stated floor price of $0.25 per share. Through December 31, 2009, we issued 4,500,000 shares of the common stock and received gross proceeds of $1,055,000. We received net proceeds of $1,183,000 through March 31, 2010 of which $191,000 was received for 1,000,000 shares during the three months ended March 31, 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

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In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

- In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

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- In August 2009 and March 2010, we received milestone payments from Velcera, Inc. of $156,250 and $62,500, respectively. We received these payments under the license and development agreement we entered into with Velcera, Inc. in June 2004.

- In May 2008, we entered into an exclusive license and supply agreement with BioAlliance Pharma SA, or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales.

- 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.

In addition, in February 2011, we completed a public offering of 1,667 shares of our Series A Preferred Stock at a price of $1,000 per share, with an original issue discount of 4%, for gross proceeds of $1.6 million. The investors also received warrants, with a 5 year term from its initial exercise date, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.15 per share; warrants, with a 1 year term, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.10 per share; and warrants, with a 5 year term from its initial exercise date, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.15 per share, which may be exercised by the holder thereof to the extent and in the same percentage that the holder exercises its 1 year warrant. The 1 year warrants are immediately exercisable, while the other warrants are only exercisable on and after February 15, 2012.

We will seek to raise additional capital in 2011 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 if 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 June 30, 2011.

Our audited financial statements for the fiscal year ended December 31, 2010 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 2011 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.

The following table sets forth our aggregate contractual cash obligations as of December 31, 2010.

	Payments Due By Period				
	Total	<1 year	1-3 years	3-5 years	5 years +
Operating leases	$ 49,712	$ 45,888	$ 3,824	—	—
Total contractual cash obligations	$ 49,712	$ 45,888	$ 3,824	$ —	$ —

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We have entered into employment agreements with key executives that provide for the continuation of salary if terminated for reasons other than cause, as defined in those agreements. These agreements generally expire upon termination for cause or when the Company has met its obligations under these agreements. As of December 31, 2010, no events have occurred resulting in the obligation of any such payments.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

Revenue Recognition

We receive revenue from our license agreements. Upfront non-refundable license fees are recognized as earned, or they are deferred and subsequently recognized into revenue on a straight-line basis over the contracted or estimated period of performance, which is typically contractual term. Milestone payments are recognized on achievement of the milestone, unless the amounts received are creditable against royalties or we have on-going performance obligations. Royalty payments, if any, will be recognized on sale of the related product, provided the royalty amounts are fixed and determinable, and collection of the related receivable is probable.

Accrued Expenses

We are required to estimate accrued expenses as part of preparing our financial statements. This process involves identifying services which have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with the production of clinical drug supplies and to contract research organizations in connection with our preclinical studies and clinical trials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs which have been incurred, or we under- or over-estimate the level of services performed or the costs of such services in a given period, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us. To date, we have been able to reasonably estimate these costs; however, if we increase the level of services performed on our behalf, it will become increasingly more difficult for us to estimate these costs, which could result in our reported expenses for future periods being too high or too low.

Stock-Based Compensation

We grant equity based awards under stock-based compensation plans. We estimate the fair value of stock options granted using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option’s expected life, price volatility of the underlying stock, risk free interest rate, and expected dividend rate. As stock-based compensation expense is based on awards ultimately expected to vest, it has been

reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Derivative Financial Instruments

We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants are now accounted for as derivatives.

Recent Accounting Pronouncements

See Note 3 in the accompanying notes to our financial statements beginning on page F-6 in this Annual Report on Form 10-K.

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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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We assessed our vulnerability to certain market risks, including interest rate risk associated with financial instruments included in cash and cash equivalents. Due to the short-term nature of our cash and cash equivalents, we have determined that the risks associated with interest rate fluctuations related to these financial instruments do not pose a material risk to us.

Item 8. Financial Statements and Supplementary Data.

Our financial statements appear in a separate section of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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, 2010. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2010, 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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. 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, 2010, our internal control over financial reporting was effective. This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm because smaller reporting companies are exempt from this requirement.

Changes in Internal Controls over Financial Reporting

During the fourth quarter 2010, 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.

As previously disclosed on a Current Report on Form 8-K on December 8, 2006, the Company had entered into an employment agreement with David H. Bergstrom, Ph.D. Dr. Bergstrom's employment agreement expired by its terms on December 4, 2009. On December 31, 2009, the Compensation Committee approved the recommendation to maintain Dr. Bergstrom's services and to continue his employment on the same terms and conditions as the employment agreement effective as of December 4, 2009 for a period of one year from the effective date with one-year renewals thereafter. On March 23, 2011, the Compensation Committee approved the recommendation to further extend Dr. Bergstrom's employment on the same terms and conditions as the original employment agreement through June 30, 2011.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our Definitive Proxy Statement for our 2011 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2010. Such information is incorporated herein by reference.

We have adopted a code of conduct that applies to our Principal Executive Officer, Principal Financial and Accounting Officer, and to all of our other officers, directors and employees. The code of conduct is available at the Corporate Governance section of our website at www.novadel.com. We intend to disclose on our website any amendments to, or waivers from, our code of conduct that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission.

Item 11. Executive Compensation.

Information required by this item will be contained in our Definitive Proxy Statement for our 2011 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2010. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in our Definitive Proxy Statement for our 2011 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2010. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our Definitive Proxy Statement for our 2011 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2010. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be contained in our Definitive Proxy Statement for our 2011 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2010. Such information is incorporated herein by reference.

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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 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.
4.2	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.
4.3	Form of Warrant	Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008.
4.4	Form of Series A Warrant	Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed with the SEC on March 31, 2010.
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	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.
10.9*	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.
10.10*	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.
10.11*	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.
10.12*	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.
10.13*	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.
10.14*	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.
10.15*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006.

10.16*	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.
10.17*	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.
10.18*	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.
10.19*	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.
10.20	Amended and Restated License and Development Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and Talon Therapeutics, Inc. (formerly known as 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.
10.21	Product Development and Commercialization Sublicense Agreement, dated as of July 31, 2007, by and among NovaDel Pharma Inc., Talon Therapeutics, Inc. (formerly known as HANA Biosciences, Inc.) 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.

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10.22	Securities Purchase Agreement, dated May 6, 2008, by and among the Company, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Investments III, L.P	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 3, 2008.
10.23+	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.
10.24+	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.
10.25+	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.
10.26+	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.
10.27	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.
10.28*	Employment Agreement, dated January 8, 2010, by and between the Company and Steven B. Ratoff	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on January 11, 2010.
10.29	Securities Purchase Agreement, dated March 31, 2010, by and among the Company and certain purchasers	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on March 31, 2010.
10.30*	Employment Agreement, dated June 8, 2010, by and between the Company and Craig Johnson	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 9, 2010.

10.31*	Amendment 2010 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan, dated April 20, 2010	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on June 10, 2010.
10.32	License Agreement, dated January 5, 2007, between NovaDel Pharma, Inc. and Kwang Dong Pharmaceuticals	Filed herewith.
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) and Rule 15d-14(a)	Furnished herewith.
31.2	Certification of Principal Financial Officer under Rule 13a-14(a) and Rule 15d-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.

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(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 29, 2011

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 and Chief Executive Officer (Principal Executive Officer)	March 29, 2011
/s/ CRAIG JOHNSON Craig Johnson	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 29, 2011
/S/ MARK J. BARIC Mark J. Baric	Director	March 29, 2011
/S/ THOMAS E. BONNEY Thomas E. Bonney	Director	March 29, 2011
/S/ CHARLES NEMEROFF Charles Nemeroff	Director	March 29, 2011

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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, 2010 and 2009, and the related statements of operations, changes in stockholders' deficiency and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009 and its results of operations and cash flows for each of the three years in the period ended December 31, 2010, 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 29, 2011

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NovaDel Pharma Inc.
Balance Sheets

Assets	December 31, 2010	December 31, 2009
Current assets:		
Cash and cash equivalents	$900,000	$2,663,000
Receivables	744,000	—
Prepaid expenses and other current assets	346,000	1,430,000
Total current assets	1,990,000	4,093,000
Property and equipment, net	221,000	324,000
Other assets	7,000	36,000
Total assets	$2,218,000	$4,453,000
Liabilities and stockholders' deficiency		
Current liabilities:		
Accounts payable	$356,000	$195,000
Accrued expenses and other current liabilities	146,000	117,000
Current portion of deferred revenue	3,259,000	4,266,000
Derivative liability	611,000	—
Current portion of capital lease obligations	—	10,000
Total current liabilities	4,372,000	4,588,000
Non-current portion of deferred revenue	3,689,000	4,202,000
Non-current portion of capital lease obligations	—	4,000
Total liabilities	8,061,000	8,794,000
Commitments and contingencies		
Stockholders' deficiency		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		
200,000,000 shares authorized, 98,681,029 and 88,343,457 issued and outstanding at December 31, 2010 and 2009, respectively	99,000	89,000
Additional paid-in capital	79,496,000	78,342,000
Accumulated deficit	(85,432,000)	(82,766,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total stockholders' deficiency	(5,843,000)	(4,341,000)
Total liabilities and stockholders' deficiency	$2,218,000	$4,453,000

See accompanying notes.

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NovaDel Pharma Inc.
Statements of Operations

	Year Ended December 31,		
	2010	2009	2008
Revenue:			
License fees	$1,519,000	$266,000	$361,000
Milestone fees	1,063,000	156,000	—
Other	244,000	—	—
Total revenue	2,826,000	422,000	361,000
Operating expenses:			
Research and development	2,786,000	2,473,000	3,878,000
General and administrative	3,008,000	4,044,000	4,722,000
Loss on assets held for sale	—	—	351,000
Total operating expenses	5,794,000	6,517,000	8,951,000
Loss from operations	(2,968,000)	(6,095,000)	(8,590,000)
Other income (expense):			
Change in derivative liability	302,000	360,000	—
Loss on disposal of fixed assets	—	(745,000)	—
Interest expense	(1,000)	(2,160,000)	(1,868,000)
Interest income	1,000	6,000	137,000
Loss before income tax benefit	(2,666,000)	(8,634,000)	(10,321,000)
Income tax benefit	—	(1,057,000)	(735,000)
Net loss	$(2,666,000)	$(7,577,000)	$(9,586,000)
Basic and diluted loss per common share	$(0.03)	$(0.12)	$(0.16)
Weighted average common shares outstanding - basic and diluted	95,618,000	61,346,000	59,592,000

See accompanying notes.

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NovaDel Pharma Inc.
Statements of Changes in Stockholders' Equity (Deficiency)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity (Deficiency)
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	60,000	72,034,000	(74,829,000)	(6,000)	(2,741,000)
Share-based compensation expense	—	—	326,000	—	—	326,000
Cumulative effect for the adoption of ASC 815-40-15 relating to outstanding warrants indexed to the entity's own stock	—	—	—	(360,000)	—	(360,000)
Restricted stock cancelled	(575,000)	—	—	—	—	—
Cashless exercise of warrants	489,114	1,000	(1,000)	—	—	—
Issuance of common stock	27,737,083	28,000	5,983,000	—	—	6,011,000
Net loss	—	—	—	(7,577,000)	—	(7,577,000)
Balance, December 31, 2009	88,343,457	89,000	78,342,000	(82,766,000)	(6,000)	(4,341,000)
Share-based compensation expense	—	—	563,000	—	—	563,000
Warrant liability	—	—	(913,000)	—	—	(913,000)
Restricted stock cancelled	(60,000)	—	—	—	—	—
Cashless exercise of warrants	297,571	—	—	—	—	—
Issuance of common stock, net of expenses	10,100,001	10,000	1,504,000	—	—	1,514,000
Net loss	—	—	—	(2,666,000)	—	(2,666,000)
Balance, December 31, 2010	98,681,029	$99,000	$79,496,000	$(85,432,000)	$(6,000)	$ (5,843,000)

See accompanying notes.

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NovaDel Pharma Inc.
Statements of Cash Flows

	Year Ended December 31,		
	2010	2009	2008
Cash Flows from Operating Activities			
Net loss	$(2,666,000)	$(7,577,000)	$(9,586,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Debt conversion to common stock expense	—	1,360,000	—
Expiration of warrants	—	(360,000)	—
Share-based compensation expense	563,000	326,000	771,000
Amortization of debt discount and deferred financing fees	—	428,000	1,711,000
Loss on assets held for sale	—	—	351,000
Loss on disposal of fixed assets	—	745,000	19,000
Depreciation and amortization	103,000	369,000	506,000
Change in derivative liability fair value	(302,000)	—	—
Changes in operating assets and liabilities:			
Receivable	(744,000)	—	—
Prepaid expenses and other current assets	1,084,000	(472,000)	151,000
Other assets	12,000	223,000	110,000
Accounts payable	161,000	(459,000)	(978,000)
Accrued expenses and other current liabilities	29,000	105,000	(1,344,000)
Deferred revenue	(1,520,000)	3,734,000	2,756,000
Net cash used in operating activities	(3,280,000)	(1,578,000)	(5,533,000)
Cash Flows from Investing Activities:			
Purchases of property and equipment	—	—	(121,000)
Proceeds from sale of fixed assets	—	41,000	—
Return of lease deposit	17,000	—	—
Net cash provided by (used in) investing activities	17,000	41,000	(121,000)
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock through private placements, net of expenses	1,514,000	1,007,000	—
Proceeds from issuance of convertible notes	—	—	4,000,000
Deferred financing costs	—	—	(238,000)
Payments of convertible note obligation	—	(1,000,000)	—
Payments of capital lease obligations	(14,000)	(135,000)	(164,000)
Net cash provided by (used in) financing activities	1,500,000	(128,000)	3,598,000
Net decrease in cash and cash equivalents	(1,763,000)	(1,665,000)	(2,056,000)
Cash and cash equivalents at beginning of year	2,663,000	4,328,000	6,384,000
Cash and cash equivalents at end of year	$900,000	$2,663,000	$4,328,000
Supplemental disclosure of cash paid for interest	$1,000	$10,000	$28,000

Supplemental disclosure of noncash investing and financing activities:			
Issuance of common stock for note conversion	—	$3,000,000	—
Issuance of common stock to convert penalties and interest	—	$657,000	—
Settlement of obligation with transfer of fixed assets	—	$267,000	
Derivative liability	$913,000	—	—

See accompanying notes.

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NovaDel Pharma Inc.
Notes to Financial Statements

Note 1 – Organization and Business

NovaDel Pharma Inc. is a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy, safety, patient compliance, and patient convenience for a broad range of prescription medications. NovaDel Pharma Inc. is a Delaware corporation. All references to "NovaDel," "we," "our," "us" or the "Company" refer to NovaDel Pharma Inc.

Note 2 – Liquidity and Basis of Presentation

We have incurred net losses of $2.7 million, $7.6 million, and $9.6 million for the years ended December 31, 2010, 2009 and 2008, respectively. Since inception, and through December 31, 2010, we have accumulated deficit of $85.4 million. As of December 31, 2010, we had $900,000 in cash and cash equivalents, and $744,000 in receivables. We collected the entire $744,000 of receivables in January and February 2011. In February 2011, we sold 1,667 shares of our preferred stock for gross proceeds of approximately $1.6 million. Based on our operating plan, our existing working capital is not sufficient to meet our cash requirements to fund our planned operating expenses and working capital requirements through December 31, 2011 without additional sources of cash.

These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Note 3 – Summary of Significant Accounting Policies

Use of Estimates
The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements, and the disclosures made in the accompanying notes to the financial statements. Actual results could differ materially from those estimates.

Reclassification
Certain reclassifications have been made to prior period amounts to conform to current period presentation.

Cash and Cash Equivalents
Cash equivalents consist of money market instruments with original maturities of three months or less when purchased. We maintain our cash and cash equivalents with two 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.

Property and Equipment
Property and equipment is stated at cost less accumulated depreciation. Depreciation is calculated on a straight-line method over the estimated useful lives of the assets (primarily five years).

Impairment of Long-lived Assets

In accordance with GAAP, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and recording the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from actual results.

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Revenue Recognition
We receive payments pursuant to our license agreements. Revenue from upfront license fee payments is recognized as earned, or it is deferred and subsequently recognized over the contractual period. Revenue from milestone payments is recognized as earned. Revenue from government grants is recognized as earned, and in the period the related expenses are incurred.

Research and Development Costs
Research and development costs are expensed as incurred.

Stock-Based Compensation
We grant equity based awards under stock-based compensation plans. We estimate the fair value of stock options granted using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option's expected life, price volatility of the underlying stock, risk free interest rate, and expected dividend rate. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Derivative Financial Instruments
We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants are now accounted for as derivatives.

Income Taxes
Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Temporary differences between financial statement and income tax reporting result primarily from net operating losses. As a result of these temporary differences, we have recorded a deferred tax asset with an offsetting valuation allowance for the same amount. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is considered more likely than not that some portion or all of the deferred tax asset will not be realized.

Loss Per Share
The Company's basic loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of December 31, 2010, 2009 and 2008, there were 30.2 million, 28.1 million, and 48.0 million common shares, respectively, issuable upon exercise of options and warrants, and the vesting of non-vested restricted common stock.

Recent Accounting Pronouncements