

NOVADEL PHARMA INC  
Form 10-K  
March 31, 2008  
**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the year ended December 31, 2007

*COMMISSION FILE NO. 001-32177*

**NOVADEL PHARMA INC.**

(Exact Name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

001-32177  
(Commission File No.)

22-2407152  
(I.R.S. Employer  
Identification No.)

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25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant's telephone number, including area code

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

**Title of each class**

**Common Stock, par value \$.001 per share**

**Name of each exchange on which registered**

**American Stock Exchange**

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

**the Exchange Act:**

**None**

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

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  No

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  No

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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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. 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   
Smaller reporting company

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

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

As of June 29, 2007, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately \$65.4 million based upon the closing sale price of \$1.15 for the Registrant's common stock, \$.001 par value, as reported by the American Stock Exchange on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 19, 2008, the issuer had 60,692,260 shares of common stock, \$.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, 2007) are incorporated by reference into Part III of this Annual Report on Form 10-K.

NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2007

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

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

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

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

**PART I**

**ITEM 1. BUSINESS.**

**GENERAL**

NovaDel Pharma Inc., a Delaware corporation, referred to herein as “we”, “us” and “our”, is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed pharmaceuticals. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have eight patents which have been issued in the U.S. and 71 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing for our product candidates.

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

- Significant prescription sales already exist;
- Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs;
- Increasing focus on products in targeted therapeutic areas, where the benefits of our technology may apply to multiple target compounds, and where distribution can be achieved with a specialized sales and marketing group; and
- Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

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

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

We have a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2007 of \$65,243,000, as compared to \$48,280,000 as of December 31, 2006. Additionally, we have had negative cash flow from operating activities of \$15,240,000 for the year ended

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December 31, 2007, \$1,782,000 for the five-months ended December 31, 2006, \$8,855,000 for the fiscal year ended July 31, 2006, and \$6,258,000 for the fiscal year ended July 31, 2005. As of December 31, 2007, we had working capital of \$3,811,000, as compared to \$18,686,000 as of December 31, 2006, representing a net decrease in working capital of approximately \$14,875,000.



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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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. Given the current level of spending, we estimate that we will have sufficient cash on hand to fund operations through the middle of the second calendar quarter, 2008. Funding for the Company's future development activities could be secured through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

Our audited financial statements for the year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in the Company.

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

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

Highlights for the year ended December 31, 2007, and additionally through the date of filing of this Form 10-K, include the following product development and business achievements:

### *Product Pipeline*

- Announced that the Company's New Drug Application for ZolpiMist™ to treat insomnia was accepted for filing by the FDA.
- Announced that Par Pharmaceuticals has been granted a sublicense for the development and commercialization of Zensana™.

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- Announced that Par Pharmaceuticals has returned the rights to NitroMist™ to us.
- Announced that two clinical studies comparing our zolpidem oral spray with zolpidem tablets met their primary pharmacokinetic and pharmacodynamic and safety objectives.

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- Announced that Hana Biosciences has notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there will be a delay in the FDA approval and commercial launch of Zensana™.

### *Intellectual Property*

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

### *Executive Team and Board of Directors*

- Appointed Mr. Steven B. Ratoff, our current Chairman of the Board, to serve as interim President and Chief Executive Officer.
- Announced that Jan H. Egberts, M.D. resigned as President, Chief Executive Officer and Director.
- Appointed Mr. Mark J. Baric as a member of the Board of Directors.
- Appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.
- Announced that Mr. Barry C. Cohen will no longer serve as Vice President, Business and New Product Development, and the execution of a related settlement/release agreement.
- Renewed the employment agreement of Mr. Michael E. Spicer as Chief Financial Officer.

## **PRODUCT DEVELOPMENT**

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

expenditures may significantly exceed management's expectations.

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

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

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

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- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals or changes in the regulatory approval process;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technologies and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We currently have six product candidates in our pipeline. One of these product candidates, Zensana™, is currently licensed to a marketing partner who will commercialize this product candidate, with us receiving milestone and royalty income from revenue upon product approval. For our approved product NitroMist™, and for ZolpiMist™ (zolpidem oral spray) and sumatriptan oral spray, currently in development, we will most likely seek marketing partners to commercialize these three product candidates, as their broad distribution will require significant resources. We are actively seeking partners for these products and would anticipate that such marketing partners would provide us with milestone payments and royalties based on revenues.

Our two remaining earlier-stage product candidates, tizanidine and ropinirole, are targeted for a specific therapeutic area: neurology. Similar to other products, we will seek to secure marketing partners, once we have generated sufficient clinical data to demonstrate their performance.

As discussed above, certain of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation.

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

<i>Approved Product</i>	<b>Active Ingredient or Class of Molecule</b>	<b>Indications</b>	<b>Stage of Development</b>	<b>Partner</b>
				-

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NitroMist™ <i>Product Candidates</i>	Nitroglycerin	Acute angina	FDA Approved	
ZolpiMist™	Zolpidem tartrate	Sleeplessness	NDA submitted; FDA acceptance January 23, 2008	-
Sumatriptan	Sumatriptan succinate	Migraines	Pilot Efficacy study complete	-
Ropinirole	Ropinirole	Idiopathic Parkinson's Disease	Clinical development	-
Tizanidine	Tizanidine hydrochloride	Spasticity	Clinical development	-
Zensana™	Ondansetron	Anti-emetic	Clinical development	Hana Biosciences/Par Pharmaceuticals

**NitroMist™ (nitroglycerin lingual aerosol).** This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceuticals, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. We are currently investigating strategic partners for this product.

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

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

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg oral spray than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the oral spray than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg oral spray appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

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





**Tizanidine oral spray.** Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including multiple sclerosis, spinal cord injury, stroke and cerebral palsy, which leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including tizanidine, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

**Ropinirole oral spray.** Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We were previously targeting an NDA submission for our ropinirole product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including ropinirole, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

**Zensana™ (ondansetron oral spray).** Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par has announced that it expects to complete clinical development on the revised formulation of Zensana™ during 2008, and expects to submit a new NDA for Zensana™ by the end of 2008.

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

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



**Propofol oral spray.** Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product candidate. On July 10, 2007, Manhattan Pharmaceuticals announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

**Veterinary.** Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist™ platform, which is based on our patented oral spray technology.

## **BUSINESS DEVELOPMENT**

To date, we have entered into license agreements with (i) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par, for the marketing rights in the U.S. and Canada for NitroMist™, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. In addition, we have entered into a sub-license agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount BioCapital, Inc., Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, as of March 19, 2008, Dr. Rosenwald may be deemed to beneficially own approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences.

In July 2007, the Company, entered into a Product Development and Commercialization Sublicense Agreement (the "Sublicense Agreement") with Hana Biosciences and Par Pharmaceutical, Inc. ("Par"), pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™ (the "Amended and Restated License Agreement") to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada.

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

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

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

- Marketing partners outside of North America for Zensana™, for which we retain marketing rights outside of North America;
- Marketing partners for our zolpidem oral spray and sumatriptan oral spray, to commercialize these products assuming that we are successful in attaining approval for these products from the FDA; and
- Additional marketing partners and strategic alliances as may be appropriate for the remaining present and future products in our development pipeline.

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

In October 2004, we entered into a 20-year license and development agreement with Hana Biosciences, whereby Hana Biosciences would develop and market our oral spray version of ondansetron, a leading anti-emetic for preventing chemotherapy-induced nausea and vomiting. Under the agreement, Hana Biosciences was granted exclusive rights to market, sell and distribute our ondansetron oral spray in the U.S. and Canada. We are entitled to receive milestone payments at several junctures of development, including completion of a pharmacokinetic study, filing of an IND, FDA acceptance of the NDA and NDA approval. In August 2005, our license and development agreement with Hana Biosciences was amended to transfer the responsibility to Hana Biosciences of selecting and managing a contract manufacturer who will provide clinical and commercial quantities of the ondansetron oral spray product. Double-digit royalties on net sales of the product may be due to us if and when the product launches. In October 2004, in exchange for \$1 million, Hana Biosciences purchased 400,000 newly issued shares of our common stock, at a price of \$2.50 per share, and has issued to us, for no additional consideration, 73,121 shares of its common stock, valued at \$500,000 based upon the average price of Hana Biosciences' common stock during the 10 business days prior to the effective date of the agreement (\$6.84 per share).

On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences.

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

**LICENSE AND SUPPLY AGREEMENT WITH PAR PHARMACEUTICAL, INC.**

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

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

**AGREEMENT WITH MANHATTAN PHARMACEUTICALS, INC.**

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In April 2003, we entered into a 10-year license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation. Manhattan Pharmaceuticals is a development stage company and has no revenues to date. The terms of the agreement require Manhattan Pharmaceuticals to achieve certain milestones and to make certain up-front license fee payments to us, the first \$500,000 of which we received from June 2003 through November 2003.

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**AGREEMENT WITH VELCERA PHARMACEUTICALS, INC. (FORMERLY VETCO)**

In June 2004, we announced the granting of an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera, a veterinary company. We received an equity stake of 529,500 shares of common stock in Velcera, along with an upfront cash technology fee of \$1,500,000 in September 2004. At the time of the signing of the agreement with Velcera it was determined that the Velcera common stock had a de minimus value. Such investment continues to be carried at its cost basis of \$0 as of December 31, 2007. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. The common stock of Denali Sciences, Inc. is not traded on any stock exchange. The agreement, which amends an earlier agreement, provides that Velcera shall make certain milestone payments to us upon the achievement of key events associated with product development. Velcera will be obligated to make additional similar payments to us for each product developed by it, and double-digit royalty payments on product sales will be due to us. Products will be formulated by Velcera, at Velcera's expense, and Velcera will fund all development and regulatory expenses.

**BUSINESS STRATEGY**

*Strategy*

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

- Significant prescription sales already exist;
- Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs;
- Increasing focus on products in targeted therapeutic areas (e.g., neurology) where the benefits of our technology may apply to multiple target compounds, and where we can achieve distribution with a small specialized sales and marketing group; and
- Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

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

*Products*

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

Our two remaining product candidates, tizanidine and ropinirole, are targeted for a specific therapeutic area: neurology. Similarly to our other products, we will seek to secure marketing partners once we have generated sufficient clinical data to demonstrate performance.

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



## **PATENTED AND PATENT PENDING DELIVERY SYSTEMS**

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

## **MARKETING AND DISTRIBUTION**

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

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

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

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

## **MANUFACTURING**

We intend to contract out the manufacturing of our product candidates. Our current facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. We will have to contract out manufacturing and/or invest additional funds in the current facility in order to provide internal manufacturing capability.

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The manufacture of our pharmaceutical product candidates is subject to cGMP prescribed by the FDA and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, Business-“Raw Materials and Suppliers” and “Government Regulation.”

On November 18, 2004, we entered into a manufacturing and supply agreement with INyX USA, Ltd, or INyX, whereby INyX will manufacture and supply our nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX will be the exclusive provider of the nitroglycerin lingual spray to us worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. Pursuant to the terms and conditions of the agreement, it will be INyX’s responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years.

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In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any assets of the Company located at INyX are protected.

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

### **RAW MATERIALS AND SUPPLIERS**

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

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

Development and regulatory approval of our product candidates are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

### **GOVERNMENT REGULATION**

#### ***FDA approval process***

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

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application or IND, which must become effective before clinical testing

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may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

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

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

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

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

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

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

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently \$1,178,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently \$65,030 per product and \$392,700 per establishment. These fees are typically increased annually.

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

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

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

### *The Hatch-Waxman Act*

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

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

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

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

### *Section 505(b)(2) New Drug Applications*

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

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.



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

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

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana™ in June 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA, and that it plans to re-direct the development plan for Zensana™ using our patent-protected European formulation of the product. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par Pharmaceutical, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. Subject to successful scale-up and manufacturing tests of the new formulation of ondansetron, Par expects to conduct the appropriate clinical trials and re-file the NDA for Zensana™ by the end of 2008. Because we rely upon Par to develop and file the NDA for Zensana™ we can give no assurances that Par will be able to re-file the NDA for Zensana™ in 2008, if at all, and ultimately receive final FDA approval. The safety and efficacy of the drug is based on a demonstration of the bioequivalence of Zensana™ to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us, Hana Biosciences, and/or Par for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences previously announced that it had not received any objections related to these patent certifications.

### ***Other Regulatory Requirements***

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

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



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

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

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

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

#### ***Physician Drug Samples***

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

## **COMPETITION**

The markets which we intend to enter are characterized by intense competition, often from organizations which are larger and/or better capitalized than us. We will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.



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

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

### **PATENTS AND PROTECTION OF PROPRIETARY INFORMATION**

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

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

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

**BUCCAL NONPOLAR SPRAYS.** On April 12, 1996, we filed an application with the U.S. Patent and Trademark Office, or the USPTO, with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the

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buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

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

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, with claims directed to the above subject matter. On April 16, 2003, European Patent No. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs (i.e., anti-histamines, steroid hormones, non-steroidal anti-inflammatories, benzodiazepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. We have filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. The Canadian Patent Office granted the application on December 27, 2005 as Canadian Patent No. 2,252,050. The allowed claims are similar to those granted by the European Patent Office.

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

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

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter. On February 2, 2005, European Patent No. 0 910 339 was granted to us with claims directed to use of polar solvent containing pump sprays containing similar drugs to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. In November 2005, Akzo Nobel N.V. filed an opposition against this patent in the European Patent Office alleging “lack of inventive step” and “insufficient disclosure.” We have filed a Response to the Opposition. The Opposition Proceeding is currently pending before the European Patent Office. We have also filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. On February 10, 2006, the Canadian Patent Office issued a Notice of Allowance for this application.

**BUCCAL NONPOLAR SPRAY FOR NITROGLYCERIN.** On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9,

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1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

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On February 21, 1997, we filed a PCT application (PCT Application No. WO 97/38687) directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive. Nevertheless, Greek Patent, GRO904055 was issued on March 18, 2004, for our nitroglycerin buccal, non-polar spray or capsule.

In October 1998, we entered the national phase in Canada. We filed a request for examination on February 7, 2002. The Canadian Patent Office issued a second office action to us dated July 11, 2005. We responded to the office action on January 11, 2006 and await further communication from the Canadian Patent Office.

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

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

On March 29, 2000, we entered the national phase in the U.S. by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions. Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application is currently being prosecuted with claims directed to the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes and methods of administering said drugs using these types of buccal spray compositions. The second divisional application was issued to us as U.S. Patent No. 6,676,931. This patent expires on October 1, 2017. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs that were not included in the claims of U.S. Patent No. 6,676,931.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has been received from the Canadian Patent Office and we have responded to that office action. Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. We filed a request for examination of this Japanese application on September 30, 2004.





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Based on the above-identified PCT application, we also entered the national phase in Europe in April 2000. The European application includes claims directed to propellant free buccal spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. We have filed three applications related to this application in Europe. The first application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant and certain classes of drugs as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. The second application included claims directed to propellant free buccal spray compositions containing certain amounts of a non-polar solvent and certain classes of drugs, as well as specific drugs in those classes. The third application included claims directed to a buccal spray composition containing certain amounts of a polar solvent, a propellant and certain classes of drugs, as well as specific drugs in those classes. Each of the above-identified European applications is currently being prosecuted.

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

**STABLE HYDROALCOHOLIC ORAL SPRAY FORMULATIONS AND METHODS.** On April 19, 2007, we filed an application with the USPTO with claims directed to hydroalcoholic spray compositions and methods. The application was published on October 25, 2007, and is currently pending. Substantive examination of the application by the USPTO has not yet begun. On April 19, 2007 we also filed a corresponding PCT application

**ANTI-MIGRAINE ORAL SPRAY FORMULATIONS AND METHODS.** On July 27, 2007 we filed an application with the USPTO with claims directed to compositions comprising a selective 5-hydroxytryptamine receptor subtype agonist and methods of treatment. The application was published on February 7, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun. On July 27, 2007 we also filed a corresponding PCT application.

**ANTIHISTAMINE SYRUP AND OINTMENT.** On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts of a polar or non-polar solvent. On May 21, 2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method. This patent expires on November 10, 2017.

**GENERAL COMMENT WITH RESPECT TO ENTERING THE NATIONAL PHASE FOR EACH OF THE FOREGOING PCT APPLICATIONS.** In addition to our patents and patent applications in the U.S., we are interested in entering the national phase and obtaining patent protection in Europe and Canada. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications in Canada and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed \$100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

**EMPLOYEES**

As of March 19, 2008, we had 14 total employees, all of whom were full-time employees.

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

NAME	AGE	POSITION WITH THE COMPANY
Mark J. Baric	49	Director
Thomas E. Bonney	43	Director
William F. Hamilton, Ph.D.	68	Director
J. Jay Lobell	45	Director
Charles Nemeroff, M.D., Ph.D.	58	Director
Steven B. Ratoff	65	Chairman of the Board of Directors, Interim President and Chief Executive Officer
David H. Bergstrom, Ph.D.	53	Senior Vice President and Chief Operating Officer
Michael E. Spicer	54	Chief Financial Officer and Corporate Secretary
Deni M. Zodda, Ph.D.	54	Senior Vice President and Chief Business Officer

**Mark J. Baric**, Director, 49. Mr. Baric was elected to the Board in February 2007. Since 2005, Mr. Baric has been the President and co-founder of CeNeRx BioPharma, Inc., a privately-held development company with a therapeutic focus on diseases of the central nervous system. In 2001 he co-founded and served, until 2005, as Chief Executive Officer and Chairman of 2ThumbZ Entertainment Inc., a privately-held company which develops and markets entertainment applications for users of handheld wireless devices and networks. From 1996 to 2001, Mr. Baric was Chairman and Chief Executive Officer of Virtus Entertainment Corporation, an emerging company in the fast-growing interactive entertainment industry. From 1990 to 1996, Mr. Baric held various leadership positions, including Chief Operating Officer and Chief Financial and Administrative Officer of Seer Technologies Inc. (now known as Cicero, Inc.), a provider of business integration software. Prior to 1990, Mr. Baric held various leadership positions at several firms, including CS First Boston and Coopers and Lybrand. Mr. Baric serves on the boards of CeNeRx BioPharma, Inc., 2ThumbZ Entertainment Inc. and Concert Technologies, a privately-held company focused on rich media technology and licensing. Mr. Baric received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. from Clarion University. He is a member of our Audit Committee and a member of our Compensation Committee.

**Thomas E. Bonney**, CPA, Director, 43. Mr. Bonney was elected to the Board in March 2005. From 2002 to the present, Mr. Bonney has been Managing Director of CMF Associates, LLC, a financial and management consulting firm. Since December 2006, Mr. Bonney has been a General Partner in West Place LLC, and West Place Restaurant Group, LLC, privately-held companies that invest in and manage hotels and real estate. Since June 2005, Mr. Bonney has been a Director of Leblon Holdings LLC, a privately-held beverage supplier and from June 2005 through July 2007 was the Chief Financial Officer of Leblon Holdings, LLC. From 2001 to 2002, he was Chief Financial Officer of Akcelerant Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touche from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is a member and chair of our Audit Committee and a member of our Corporate Governance and Nominating Committee.



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**William F. Hamilton**, Ph.D., Director, 68. Dr. Hamilton was elected to the Board in March 2003. In January 2006, Dr. Hamilton was appointed Lead Independent Director. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. He serves as a director of Neose Technologies, Inc., a publicly-traded company developing proprietary drugs. Dr. Hamilton is also a director of Yaupon Therapeutics, Inc., a privately-held specialty pharmaceutical company that develops small molecule pharmaceuticals licensed from under-served academic laboratories, Avid Radiopharmaceuticals, Inc., a privately-held clinical-stage product-focused molecular imaging company and Neuro Diagnostic Devices, a privately-held development-stage medical device company. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of our Audit Committee and a member and chair of our Corporate Governance and Nominating Committee.

**J. Jay Lobell**, Director, 45. Mr. Lobell was elected to the Board in December 2005. Mr. Lobell has served as Chief Executive Officer, Secretary and a member of the Board of Directors of Paramount Acquisition Corp. since October 2005. Mr. Lobell has served as President and Chief Operating Officer of Paramount BioCapital Asset Management, Inc. and Paramount Biosciences, LLC since January 2005, and is a registered representative of Paramount BioCapital, Inc. Mr. Lobell also serves as President and Secretary of Sitka Sciences, Inc. and Norton Sound Acquisition Corp. which are affiliates of Paramount BioCapital, Inc. From 1996 until January 2005, Mr. Lobell was a partner at Covington & Burling, a law firm. Mr. Lobell received his B.A. from Queens College and his J.D. from Yale Law School. Mr. Lobell is a director of Innovive Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, and Chem Rx Corporation, a publicly-traded long-term care pharmacy, as well as several private biotechnology companies. Mr. Lobell is a member and chair of our Compensation Committee.

**Charles Nemeroff**, M.D., Ph.D., Director, 58. Dr. Nemeroff was elected to the Board in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia, since 1991. Dr. Nemeroff serves on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals, Forest Laboratories, Janssen and Quintiles. In 2002, he was elected to the Institute of Medicine of the National Academy of Sciences. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University, his Ph.D. and post doctorate training from the University of North Carolina and his M.D. from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory Board. He is also a member of our Compensation Committee and is a member of our Corporate Governance and Nominating Committee.

**Steven B. Ratoff**, Chairman of the Board, Interim President and Chief Executive Officer, 65. Mr. Ratoff was elected to the Board in January 2006 and was elected Chairman of the Board on September 15, 2006. He was appointed as Interim President and Chief Executive Officer of NovaDel on July 23, 2007. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest Investments, a health care venture capital firm. Mr. Ratoff has been a director, since May 2005, and was Chairman of the Board, from September 2005 to October 2006, of Torrey Pines Therapeutics Inc. (formerly Axonyx Inc.), a NASDAQ development stage pharmaceutical company. Mr. Ratoff served as a director of Inkin Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December, 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a publicly-traded diversified manufacturer of consumer products. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

**David H. Bergstrom**, Ph.D., Senior Vice President and Chief Operating Officer, 53. Dr. Bergstrom joined NovaDel in December 2006 as Senior Vice President and Chief Operating Officer. From 1999 to November 2006, Dr. Bergstrom served in several capacities at Cardinal Health, Inc., including Vice President, Research & Development and Senior Vice President and General Manager. From 1998 to 1999, Dr. Bergstrom was Vice President of Pharmaceutical & Chemical Development at Guilford Pharmaceuticals Inc. Dr. Bergstrom was employed by Hoechst Marion Roussel, Inc. as the Director of Pharmaceutical and Analytical Sciences from 1996 to 1998. Dr. Bergstrom served as Director of Pharmaceutical and Analytical Development for the predecessor company, Hoechst-Roussel Pharmaceuticals Inc., from 1991 to 1996, and Group Manager, Formulations, Pharmaceutical Research from 1990 to 1991. Prior thereto, Dr. Bergstrom held various positions at Ciba-Geigy Corporation. Dr. Bergstrom received his Ph.D. in Pharmaceutics at the University of Utah in 1985. In addition, he received his M.S. in Pharmaceutical Chemistry at the University of Michigan in 1982 and his B.S. degree in Pharmacy in 1978 at Ferris State University.



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**Michael E. Spicer**, CPA, Chief Financial Officer and Corporate Secretary, 54. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004 and was named Corporate Secretary in April 2006. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.). From September 1998 to December 2001, Mr. Spicer served as Vice President, Chief Financial Officer of Lifecodes Corporation until it was acquired by Orchid. Mr. Spicer is a Certified Public Accountant and holds an undergraduate degree in Accounting from the University of Virginia and an M.B.A. from Harvard Business School.

**Deni M. Zodda**, Ph.D., Senior Vice President and Chief Business Officer, 54. Dr. Zodda joined NovaDel in February 2007 as Senior Vice President and Chief Business Officer. From May 2006 to February 2007, Dr. Zodda was Principal of Medignostica, LLC, a consulting firm he owns which provided business development services to various clients and was acting Chief Executive Officer of StemCapture, Inc., a privately-held stem cell research company. From 2000 to May 2006, Dr. Zodda served in varying capacities, including Senior Vice President, Business Development and Principal Financial Officer of Discovery Laboratories, Inc. From 1998 to 2000, Dr. Zodda served as Managing Director of the Life Sciences Practice at KPMG. During the course of his career, Dr. Zodda also held senior management positions in business development, marketing and commercial operations at Cephalon, Inc., Wyeth, Baxter International Inc. and SmithKline Beckman, Inc. Dr. Zodda received his M.B.A. in Marketing and Finance from the University of Santa Clara in 1986, his Ph.D. in Biology from the University of Notre Dame in 1980 and his B.S. in Biology from Villanova University in 1975.

### AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the Commission. You may read and copy any document we file with the Commission at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Our Commission filings are also available to the public from the Commission's Website at "<http://www.sec.gov>." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to [mspicer@novadel.com](mailto:mspicer@novadel.com) or contact Michael Spicer, our Chief Financial Officer at 25 Minneakoning Road, Flemington, New Jersey, 08822 or at 908-782-3431, ext. 2550.

We maintain a website at "<http://www.novadel.com>" (this is not a hyperlink; you must visit this website through an Internet browser). Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

**ITEM 1A. RISK FACTORS**

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

***RISKS RELATED TO OUR BUSINESS***

**OUR AUDITORS HAVE EXPRESSED SUBSTANTIAL DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN.**

Our audited financial statements for the year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in the Company.

**WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION IN THE NEAR TERM.**

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. 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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. Given the current level of spending, we estimate that we will have sufficient cash on hand to fund operations through the middle of the second quarter, 2008. Funding for the Company's future development activities could be secured through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

**WE MAY NEED ADDITIONAL CAPITAL TO FUND OUR OPERATIONS UNTIL WE ARE ABLE TO GENERATE A PROFIT.**

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

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007, we do not expect that our revenue and/or cash will cover our expenses during the next twelve months. As a result, we will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We 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

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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.

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

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

We will continue to maintain current levels of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. We believe that at the current rate of spending, we should have sufficient cash funds to maintain our present operations through the middle of the second quarter 2008.

**WE ARE A PRE-COMMERCIALIZATION COMPANY, HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE.**

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

We had an accumulated deficit as of December 31, 2007 of approximately \$65.2 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately \$17.0 million for the year ended December 31, 2007, \$3.8 million for the five months ended December 31, 2006, \$10.1 million for the fiscal year ended July 31, 2006 and \$9.5 million for the fiscal year ended July 31, 2005. Additionally, we have reported negative cash flows from operations of approximately \$15.2 million for the year ended December 31, 2007, \$1.8 million for the five months ended December 31, 2006, \$8.9 million for the fiscal year ended July 31, 2006 and \$6.3 million for the fiscal year ended July 31, 2005. We anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such

time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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

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

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

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance. Our most recent new product candidates, tizanidine and ropinirole, are focused on the neurology segment, where we believe that the benefits of our proprietary drug delivery technology may apply to a number of different pharmaceutical products.

On November 3, 2006, we announced that the FDA has approved our NitroMist™ (nitroglycerin lingual aerosol) for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist™ is our first approval that utilizes our proprietary oral spray technology.

Through July 31, 2007, our ondansetron oral spray product candidate, Zensana™ was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana™. Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for filing by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar year 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We completed pilot pharmacokinetic studies of certain of our product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, propofol and zolpidem. In addition, in September and October 2006, we completed a pharmacokinetic study of our improved oral spray formulation of sumatriptan and zolpidem, respectively. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific oral spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If desired therapeutic blood levels are not achieved, it could result in the need to reformulate the oral spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

We have also completed pilot pharmacokinetic studies for two antihistamine oral sprays (loratadine and clemastine), an estradiol oral spray, an alprazolam oral spray and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on these product candidates has been put on hold.

We have also commenced formulation work on two new product candidates, tizanidine oral spray and ropinirole oral spray.

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

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

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

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

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. As of March 19, 2008, Dr. Rosenwald beneficially owns approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the American Stock Exchange, or AMEX, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. Refer to Note 6 "Related Party Transactions and License and Development Agreements" of the Financial Statements included in this Annual Report for additional information. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald or Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

**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. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities. See “Risk Factors - We Will Require Significant Capital For Product Development And Commercialization” and “Our Strategy Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates And We May Require Additional Collaboration Agreements. If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products.”

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

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

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

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of calendar 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. We have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

**WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.**

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

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

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

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

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

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

**WE ARE DEPENDENT ON OUR SUPPLIERS.**

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX USA, Ltd., which intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. On July 3, 2007, INyX, our manufacturer for our NitroMist™ product candidate, announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any limited assets of NovaDel at the manufacturer's facility are protected.

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

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

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

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

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





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

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

**WE FACE INTENSE COMPETITION.**

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

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

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

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

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

**THE CLINICAL TRIAL AND REGULATORY APPROVAL PROCESS FOR OUR PRODUCTS IS EXPENSIVE AND TIME CONSUMING, AND THE OUTCOME IS UNCERTAIN.**

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

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

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects.

The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist™, the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. or elsewhere. If the FDA and other regulators do not approve any one or more of our products under development, we will not be able to market such products.

**WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.**

In both the U.S. and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include government health administration authorities, managed care providers and private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

**OUR STRATEGY INCLUDES ENTERING INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES FOR CERTAIN OF OUR PRODUCT CANDIDATES AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PROPOSED PRODUCTS.**

Our strategy for the completion of the required development and clinical testing of certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products.

Through June 30, 2007, we entered into strategic license agreements with Hana Biosciences, for the marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par for the marketing rights in the U.S. and Canada for our nitroglycerin oral spray, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. Subsequent to June 30, 2007, the following events occurred with respect our strategic license agreements:

On July 10, 2007, Manhattan Pharmaceuticals announced that as part of its change in strategic focus it intends to pursue appropriate out-licensing opportunities for this product candidate.

On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, or the Sublicense Agreement, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™, our oral spray version of ondansetron. In connection therewith, we and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™, or the Amended and Restated License Agreement, to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, with us able to collaborate on development in certain instances. We retain its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ or payments or other fees from a sublicense and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by us in connection with execution of the original License Agreement.

On July 31, 2007, we and Par agreed to terminate the Development, Manufacturing and Supply Agreement, dated July 28, 2004, or the DMS Agreement, relating to NitroMist™. Under the DMS Agreement, Par had exclusive rights to market, sell and distribute NitroMist™ in the U.S. and Canada, with us entitled to royalty payments based upon a percentage of net sales. We are currently investigating strategic partners for the commercialization of NitroMist™.



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

**IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, OTHER COMPANIES COULD USE OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OTHER COMPANIES COULD PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS.**

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

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect our trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the U.S. and in other countries.

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

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

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

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

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

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

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

### **EVEN IF WE OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE SUFFICIENTLY BROAD AND OTHERS COULD COMPETE WITH US.**

We, and the parties licensing technologies to us, have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Currently, we have eight patents which have been issued in the U.S. and 71 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the USPTO or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

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

**INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES COULD LIMIT OUR ABILITY TO MARKET OUR PRODUCTS.**

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

**IF WE CANNOT MEET REQUIREMENTS UNDER OUR LICENSE AGREEMENTS, WE COULD LOSE THE RIGHTS TO OUR PRODUCTS.**

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

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

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

**WE RELY ON CONFIDENTIALITY AGREEMENTS THAT COULD BE BREACHED AND MAY BE DIFFICULT TO ENFORCE.**

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

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

**WE ARE DEPENDENT ON EXISTING MANAGEMENT AND BOARD MEMBERS.**

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





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On January 17, 2006, we announced the election of Mr. Steven B. Ratoff as a member of our Board.

On April 24, 2006, Ms. Jean Frydman ceased to serve as Vice President, General Counsel and Corporate Secretary.

On September 15, 2006, our Board appointed Steven B. Ratoff as Chairman of the Board, with Dr. Egberts remaining a member of our Board.

On December 4, 2006, our Board appointed David H. Bergstrom, Ph.D. as Senior Vice President and Chief Operating Officer.

On January 4, 2007, Mr. Barry Cohen ceased to serve as Vice President, Business and New Product Development.

On February 2, 2007, we announced the election of Mr. Mark J. Baric as a member of our Board, effective February 1, 2007.

On February 22, 2007, our Board appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.

On July 23, 2007, our Board accepted the resignation of Jan H. Egberts, M.D., President, Chief Executive Officer and Director, effective July 25, 2007.

On July 23, 2007, our Board appointed Steven B. Ratoff, our current Chairman, as Interim President and Chief Executive Officer, effective July 25, 2007.

On December 14, 2007, our Board renewed the employment agreement of Michael E. Spicer, as Chief Financial Officer and Corporate Secretary, effective December 20, 2007.

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

### ***RISKS RELATED TO OUR COMMON STOCK***

#### **WE MAY RECEIVE NOTICE FROM THE AMERICAN STOCK EXCHANGE THAT WE FAIL TO COMPLY WITH CERTAIN OF ITS CONTINUED LISTING STANDARDS, WHICH MAY RESULT IN A DELISTING OF OUR COMMON STOCK FROM THE EXCHANGE.**

Our common stock is currently listed for trading on the American Stock Exchange, or AMEX, and the continued listing of our common stock on the AMEX is subject to our compliance with a number of listing standards. These listing standards include the requirement for maintaining stockholders' equity of at least \$6,000,000. As of December 31, 2007, our net worth position was \$4,174,000, which is below the minimum net worth continued listing requirement. Unless we can increase our net worth position above the required minimum, we may receive notice from the AMEX informing us that we are not in compliance with the AMEX listing standard, and we may be required to submit a plan to the AMEX advising the actions we have taken, or will take, that would bring us into compliance with all of the continued listing standards. If we are not in compliance with the continued listing standards at the end of the plan period, or if we do not make progress consistent with the plan during the plan period, the AMEX staff may initiate delisting proceedings. There can be no assurance that we will be able to make progress consistent with such plan.

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

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

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of March 19, 2008, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 20% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald has the ability to designate an individual to serve on our Board and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell has been deemed to be an independent director by our Board on September 15, 2006.

Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

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

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

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks set forth in these Risk Factors and other reports, including this Annual Report and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the AMEX since May 11, 2004 under the symbol "NVD". Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board<sup>®</sup> of the National Association of Securities Dealers, Inc. During the year ended December 31, 2007, the closing price of our common stock has ranged from \$0.21 to \$1.81. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the year ended December 31, 2007, the average daily trading volume in our common stock was approximately 151,000 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

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

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

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

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

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

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

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

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

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

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of March 19, 2008, there were 60,692,260 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of March 19, 2008, we had outstanding stock options and warrants to purchase approximately 35.1 million shares of common stock, the exercise prices of which range between \$0.45 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.

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

Plan	Shares Authorized	Options Outstanding at March 19, 2008	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000	—	Plan Closed
1997 Stock Option Plan	500,000	100,000	—	Plan Closed
1998 Stock Option Plan	3,400,000	1,619,300	1,485,700	—
2006 Equity Incentive Plan	6,000,000	4,116,800	683,200	—
Non-Plan	n/a	2,553,200	n/a	—

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

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

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

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

**SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.**

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



**LIMITATION ON DIRECTOR/OFFICER LIABILITY.**

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

**WE HAVE NO HISTORY OF PAYING DIVIDENDS ON OUR COMMON STOCK.**

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

**PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW COULD DETER A CHANGE OF OUR MANAGEMENT WHICH COULD DISCOURAGE OR DELAY OFFERS TO ACQUIRE US.**

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

**SALES OF LARGE QUANTITIES OF OUR COMMON STOCK, INCLUDING THOSE SHARES ISSUABLE IN CONNECTION WITH PRIVATE PLACEMENT TRANSACTIONS, COULD REDUCE THE PRICE OF OUR COMMON STOCK.**

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

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

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

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

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

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

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

As of March 19, 2008, we have 60,692,260 shares of common stock issued and outstanding and approximately 35.1 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

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

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

### **WE HAVE BROAD DISCRETION AS TO THE USE OF THE PROCEEDS FROM THE DECEMBER 2006 PRIVATE PLACEMENT AND MAY USE THE PROCEEDS IN A MANNER WITH WHICH YOU DISAGREE.**

Our Board and management will have broad discretion over the use of the net proceeds of the December 2006 private placement. Stockholders may disagree with the judgment of the Board and management regarding the application of the proceeds of the December 2006 private placement. We cannot predict that investments of the proceeds will yield a favorable, or any, return.

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

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





**THE UNCERTAINTY CREATED BY CURRENT ECONOMIC CONDITIONS AND POSSIBLE TERRORIST ATTACKS AND MILITARY RESPONSES THERETO COULD MATERIALLY ADVERSELY AFFECT OUR ABILITY TO SELL OUR PRODUCTS, AND PROCURE NEEDED FINANCING.**

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

**OUR INABILITY TO MANAGE THE FUTURE GROWTH THAT WE ARE ATTEMPTING TO ACHIEVE COULD SEVERELY HARM OUR BUSINESS.**

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

- We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.
- We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel.

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

**WE MAY BE OBLIGATED, UNDER CERTAIN CIRCUMSTANCES, TO PAY LIQUIDATED DAMAGES TO HOLDERS OF OUR COMMON STOCK.**

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

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

None.

**ITEM 2. PROPERTIES.**

Our executive offices, laboratory, and warehousing space are located at 25 Minneakoning Road, Flemington, New Jersey, known as the New Facility. The New Facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease, expiring in August 2013. Presently, we are only occupying a portion of our space in the New Facility. Through the lease expiration date of December 31, 2005, we also occupied approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey, known as the Old Facility, which also formerly housed our executive offices. During the five months ended December 31, 2006, we paid rent for the New Facility of approximately \$184,000. During the year ended December 31, 2007, we paid rent for the New Facility of approximately \$443,000. The New Facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. With the expiration of the lease on the Old Facility, we have contracted out manufacturing for our product candidates. The manufacture of our product candidates is subject to cGMP prescribed by the Food & Drug Administration, or FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, "Business- Raw Materials and Suppliers" and Business-Government Regulations."

**ITEM 3. LEGAL PROCEEDINGS.**

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

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

None.

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

Our common stock is traded on the American Stock Exchange, or AMEX, under the ticker symbol "NVD" since May 11, 2004. The following table sets forth the range of high and low closing sales prices of our common stock as reported by the AMEX during the year ended December 31, 2007, the five months ended December 31, 2006 and for each fiscal quarter for the fiscal years ended July 31, 2006 and 2005.

	<u>CLOSING SALE PRICES</u>	
	<u>(\$)</u>	
	<u>HIGH</u>	<u>LOW</u>
<b>YEAR ENDED DECEMBER 31, 2007</b>		
First Quarter (January 1, 2007 through March 31, 2007)	1.81	1.30
Second Quarter (April 1, 2007 through June 30, 2007)	1.33	1.02
Third Quarter (July 1, 2007 through September 30, 2007)	1.11	0.50
Fourth Quarter (October 1, 2007 through December 31, 2007)	0.54	0.21
<b>FIVE MONTHS ENDED DECEMBER 31, 2006</b>		
First Quarter (August 1, 2006 through October 31, 2006)	1.35	1.13
Two Months Ended December 31, 2006	1.86	1.24
<b>FISCAL 2006</b>		
First Quarter (August 1, 2005 through October 31, 2005)	1.85	1.21
Second Quarter (November 1, 2005 through January 31, 2006)	1.44	1.16
Third Quarter (February 1, 2006 through April 30, 2006)	1.90	1.22
Fourth Quarter (May 1, 2006 through July 31, 2006)	1.80	1.11

The last closing sales price of our common stock as reported on the AMEX on March 19, 2008 was \$0.32. As of March 19, 2008, there were approximately 115 record holders of our common stock.

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



**EQUITY COMPENSATION PLANS**

The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2007.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	5,876,000	\$ 1.66	3,269,000
Equity compensation plans not approved by security holders	2,553,000	1.87	—
Total	8,429,000	\$ 1.69	3,269,000

**PERFORMANCE GRAPH**

The graph below compares changes in the cumulative total stockholder return (change in stock price plus reinvested dividends) for the period from July 31, 2002 through December 31, 2007 of an initial investment of \$100 invested in (a) NovaDel Pharma Inc.'s common stock, (b) the Total Return Index for the AMEX Composite and (c) the Research Data Group (RDG) Microcap Pharmaceutical Index. Total Return Index values are prepared by the Research Data Group. The stock price performance is not included to forecast or indicate future price performance.

	<b>7/02</b>	<b>7/03</b>	<b>7/04</b>	<b>7/05</b>	<b>7/06</b>	<b>12/06</b>	<b>12/07</b>
<b>NovaDel Pharma Inc.</b>	\$ 100.00	\$ 119.41	\$ 100.59	\$ 73.53	\$ 70.59	\$ 96.47	\$ 14.12
<b>AMEX Composite</b>	\$ 100.00	\$ 110.80	\$ 143.68	\$ 190.27	\$ 230.38	\$ 249.13	\$ 290.15
<b>RDG MicroCap Pharmaceutical</b>	\$ 100.00	\$ 160.07	\$ 132.98	\$ 120.17	\$ 98.53	\$ 89.04	\$ 52.15

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.**

The following Selected Financial Data should be read in conjunction with our Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report on Form 10-K. The data set forth below with respect to our Statements of Operations for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006, and 2005 and the Balance Sheet data as of December 31, 2007, December 31, 2006 and fiscal year ended July 31, 2006 are derived from our Financial Statements which are included elsewhere in this Annual Report on Form 10-K and are qualified by reference to such Financial Statements and related Notes thereto. The data set forth below for the year ended December 31, 2006 and for the five months ended December 31, 2005, are unaudited. In Management's Discussion and Analysis of Financial Condition and Results of Operations, the year ended December 31, 2007 is compared to the unaudited year ended December 31, 2006, and the five months ended December 31, 2006 are compared to the unaudited five months ended December 31, 2005. There are no seasonal or other significant factors which affect comparability. The data set forth below with respect to our Statements of Operations for the fiscal years ended July 31, 2004, 2003 and 2002 and the Balance Sheets data as of July 31, 2006, July 31, 2005, July 31, 2004 and 2003 are derived from our Financial Statements, which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

Statement of	Five Months Ended							
	Years Ended December 31,		December 31,		Years Ended July 31,			
Operations Data:	2007	2006	2006	2005	2006	2005	2004	2003
		(unaudited)		(unaudited)				
Total Revenues	\$ 469,000	\$ 3,280,000	\$ 2,067,000	\$ 677,000	\$ 1,890,000	\$ 439,000	\$ 466,000	\$ 2,000
Total Expenses	18,656,000	13,544,000	6,519,000	5,429,000	12,454,000	10,217,000	7,119,000	7,091,000
Loss from Operations	(18,187,000 )	(10,264,000 )	(4,452,000 )	(4,752,000 )	(10,564,000 )	(9,778,000 )	(6,653,000 )	(7,089,000 )
Interest Income	632,000	337,000	180,000	67,000	224,000	87,000	98,000	49,000
Income Tax Benefit	(658,000 )	(467,000 )	(467,000 )	(256,000 )	(256,000 )	(241,000 )	(214,000 )	(84,000 )
Net Loss	\$ (16,963,000 )	(9,460,000 )	\$ (3,805,000 )	(4,429,000 )	\$ (10,084,000 )	\$ (9,450,000 )	\$ (6,341,000 )	\$ (6,956,000 )
Basic and Diluted Loss Per Common Share	\$ (.29 )	\$ (.20 )	\$ (.08 )	\$ (.11 )	\$ (.23 )	\$ (.27 )	\$ (.24 )	\$ (.45 )
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	59,497,000	46,732,000	49,522,000	40,619,000	43,000,000	34,808,000	26,269,000	15,419,000



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	December 31,		July 31,			
<b>BALANCE SHEET</b>	<b>2007</b>	<b>2006</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>DATA:</b>						
Cash, cash equivalents, and short-term investments	\$ 6,384,000	\$ 20,276,000	\$ 10,138,000	\$ 8,223,000	\$ 8,377,000	\$ 3,086,000
Total Assets						