NOVADEL PHARMA INC
Form 10KSB
October 31, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

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

For the fiscal year ended July 31, 2005

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES

EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.

(Name of small business as specified in its charter)

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

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Issuer s telephone number, including area code

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

Title of each class	**Name of exchange on which registered**
COMMON STOCK, PAR VALUE $.001 PER SHARE	**American Stock Exchange**

Securities registered pursuant to Section 12(g) of

the Exchange Act:

COMMON STOCK, PAR VALUE $.001 PER SHARE

Check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No __

Check if there is no disclosure of delinquent filings pursuant to Item 405 of Regulation S-B contained herein, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. [ ].

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

State issuer s revenues for its most recent fiscal year: $439,000

As of October 1, 2005, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $ 52,335,000 based upon the closing sale price of $1.75 for the Registrant s Common Stock, $.001 par value, as reported by the American Stock Exchange on that date. Common Stock held by each officer and director and by each person known to the registrant who owned 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of October 1, 2005, the issuer had 40,597,318 shares of Common Stock, $.001 par value, outstanding.

Transitional Small Business Disclosure Format (Check One) Yes __ No X

NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-KSB

FOR THE FISCAL YEAR ENDED JULY 31, 2005

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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 includes forward-looking statements , including statements regarding the expectations, beliefs, intentions or strategies for the future and our internal controls and procedures and outstanding financial reporting obligations and other accounting issues. We intend 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 our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the 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 we are developing; possible changes in our financial condition; the progress of our 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 our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research and development programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the risks related to our internal controls and procedures.

Except to the extent required by applicable laws or rules, we do not undertake any obligation or duty to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

GENERAL

NovaDel Pharma Inc., a Delaware corporation, is engaged in the development of novel application drug delivery systems for presently marketed prescription, over-the-counter (OTC) and veterinary drugs. NovaDel Pharma Inc. was originally incorporated as Pharmaconsult in the State of New Jersey on January 21, 1982. In 1991 we changed our name to Flemington Pharmaceutical Corporation. On November 25, 1998, Flemington Pharmaceutical Corporation was incorporated in the State of Delaware. On January 29, 1999, Flemington Pharmaceutical Corporation, the New Jersey corporation, merged into Flemington Pharmaceutical Corporation, the Delaware Corporation. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

Our patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and greatly accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on making it available for drugs that are already available and proven in the marketplace. In addition to increasing the bioavailability of a drug by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary drug delivery system potentially offers the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iii) improved dosage reliability; (iv) allowing medication to be taken without water; and (v) improved patient convenience and compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we continue to develop a number of such products through collaborative arrangements with pharmaceutical and veterinary companies, with such pharmaceutical companies providing the funding for the development of specified drug products. To date, we have entered into license agreements with (i) Manhattan Pharmaceuticals, Inc., in connection with propofol, (ii) Velcera Pharmaceuticals, Inc., in connection with veterinary applications for currently marketed veterinary drugs, (iii) Par Pharmaceutical, Inc., for the marketing rights in the United States and Canada for our nitroglycerin lingual aerosol, and (iv) Hana Biosciences Inc., for the marketing rights in the United States and Canada for our ondansetron oral spray.

We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally. The lack of any such further arrangements and our limited revenues and low level of working capital has restricted our ability to pursue aggressively our product development strategy. We will require additional financing and/or additional alliances with well-funded development partners to undertake and maintain our business plan.

At our inception in 1982, NovaDel, then known as Pharmaconsult, consulted to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992, we used our consulting revenues, together with the proceeds of offerings of our equity securities, to fund our own product development activities. Our focus on developing our own products 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 the focus of our business. See Risk Factors, We are Controlled by Current Stockholders, Officers and Directors; Item 12. Certain Relationships and Related Transactions; Note 2. Liquidity and Basis of Presentation; and Note 5, Related party Transactions.

On May 11, 2004, our common stock was listed for trading on the American Stock Exchange (AMEX) under the symbol NVD .

PRODUCT DEVELOPMENT

The Company has identified six (6) priority products for development, namely nitroglycerin, sumatriptan, alprazolam, zolpidem, ondansetron and propofol. In addition, the Company is developing oral spray products targeted to the animal health market. The Company intends to continue to identify and pursue additional product candidates for development.

CARDIOVASCULAR (NITROGLYCERIN)

On June 1, 2005, the Company received an approvable letter from the Food & Drug Administration (FDA) regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol), indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The Company believes that FDA approval is possible once the Company completes its previously agreed-to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. NovaDel has partnered with Par Pharmaceutical Companies, Inc., who has exclusive rights to market, sell and distribute NitroMist in the United States and Canada. Manufacturing of the product will occur at the Manati, Puerto Rico facility of INyX, Inc. NitroMist is a pending trademark of Par Pharmaceutical Companies, Inc.

MIGRAINE (SUMATRIPTAN) ORAL SPRAY

We have formulated a sumatriptan oral spray and performed a pilot pharmacokinetic study thereof during the second quarter of calendar year 2004. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline. Imitrex® is a registered trademark for GlaxoSmithKline, Inc. On October 13, 2004, we announced the preliminary results from such pharmacokinetic study. The study indicated that the sumatriptan oral spray achieved serum concentrations of sumatriptan in the therapeutic range. The pilot pharmacokinetic study involved nine healthy, fasting volunteers and was conducted in Europe. The study was designed to evaluate the pharmacokinetic profile of various doses of a sumatriptan oral spray (dose range: 2.5 mg - 30 mg) in comparison to the 50 mg oral Imitrex® tablet and 6 mg subcutaneous Imitrex® injection. For a majority of doses, we successfully delivered sumatriptan via the oral spray into the expected therapeutic range of serum concentrations. The study demonstrated a clear dose-concentration relationship for major pharmacokinetic parameters over the evaluated range of oral spray doses from 2.5 to 30 milligrams. Dose-normalized peak serum concentrations (Cmax) and areas-under-the-curve (AUC) reached with some of the doses were at least similar to the 50 mg sumatriptan (Imitrex®) tablet in this study, and appear to be greater than those published for the approved 20 mg Imitrex® nasal spray (note that the nasal spray was not included in NovaDel s study). Absorption of the oral spray through the oral mucosa was demonstrated by the observation that for some doses, overall bioavailability of sumatriptan appeared to be greater than previously reported for that of either the tablet or nasal spray formulations. Additionally, double concentration peaks detected in a number of subjects with the oral spray provided further evidence of initial drug absorption through the oral mucosa. Drug levels in what is regarded as the therapeutic range were achieved in as little as 9 to 15 minutes in a number of subjects with the oral spray. Furthermore, the mean time to reach maximal serum concentrations (Tmax) at the 15 mg oral spray dose was approximately 20 minutes shorter than that achieved with the 50 mg Imitrex® tablet in this study. The total amount of drug delivered over the first 30 minutes post-dosing (as measured by AUC normalized for dose) was approximately 40% higher for the 15 mg oral spray dose when compared to the 50 mg Imitrex® tablet.

The mean concentration levels reached at 3, 6 and 9 minutes post-dosing were appreciably higher (162%, 122% and 45% increase, respectively) for the 30 mg spray dose administered sublingually when compared to the 50 mg Imitrex® tablet. The Tmax seen with the spray (< 1 hr) was faster than that reported for the tablet at 25, 50, or 100 mg in migraine sufferers (~1.5 hrs). The sumatriptan oral spray had a favorable safety profile and was well-tolerated. None of the nine subjects dropped out of the study. We plan to take the oral spray version of sumatriptan into full development. On August 10, 2005, the Company met with the FDA to discuss the strategy for a clinical development program that could support the submission of an NDA under the provisions of section 505(b)(2) of the Federal Food, Drug & Cosmetics Act.

ANXIOLYTIC (ALPRAZOLAM) ORAL SPRAY

We have formulated an alprazolam oral spray and performed a pilot pharmacokinetic (PK) study thereof during the fourth quarter of calendar year 2004. Alprazolam is the active ingredient in Xanax® which is marketed by Pfizer, Inc. (Pfizer) and is also available in generic versions. Xanax® is a registered trademark of Pfizer. The study was designed to evaluate the PK profiles of various doses of NovaDel s oral spray compared to a 0.5 mg alprazolam tablet. NovaDel achieved its goal of delivering alprazolam via oral spray to rapidly achieve blood levels in the same therapeutic range delivered by the currently marketed oral tablet. With a 1 mg dose, the oral spray demonstrated a faster rate of absorption as evidenced by the mean time to achieve therapeutic drug levels (greater than or equal to 0.5 ng/mL) --- 15 minutes vs. 35 minutes for the 0.5 mg tablet --- and by the higher percentage of Cmax achieved at earlier time points (for example, 38.5% at 12 minutes vs. 18.8% for the oral tablet; the difference is statistically significant). The study was conducted using 9 healthy, fasting male volunteers. Each volunteer was given a 0.5 mg oral tablet and three doses of the oral spray alprazolam --- 0.25 mg, 0.75 mg, and 1mg. The doses were administered in a Phase I research unit at higher levels each week. Plasma alprazolam levels were measured and analyzed for standard PK parameters. Since the study was conducted with healthy volunteers rather than in patients with anxiety, it was not designed to evaluate the anxiolytic properties of the drug. Nonetheless, certain pharmacodynamic effects of the treatments were assessable at 30 and 60 minutes post-dosing. Based on two self-rating instruments designed to measure anxiety/tension and sleepiness/drowsiness levels, all oral spray groups achieved numerically greater scores than the tablet on both relaxation and drowsiness parameters in 30 minutes. Despite the small sample size, some of the detected differences reached statistical significance. Differences in pharmacodynamic effects were still statistically significant at 60 minutes post-dosing. For example, 56% and 89% of the subjects using the 0.75 mg and 1 mg oral sprays, respectively, reported feeling much more sleepy/drowsy, compared to 0% following the oral tablet. A clear dose-response PK relationship was established over the entire range of oral spray doses studied, as evidenced by the area-under-the-curve (AUC). The maximum serum concentration (Cmax) achieved by the oral spray at each dose level was also dose-proportional. Relative bioavailability of oral spray doses was comparable to that of the oral tablet. None of the subjects in the study terminated their participation for any safety or tolerability reasons. NovaDel s vision for an alprazolam oral spray is one that could be used by patients prone to suffering from anxiety in the face of certain predictable stimuli (e.g., closed-in spaces, airplane flight, public speaking, etc.). Such patients could successfully navigate such settings by dosing just prior to the event or at the moment when they encounter such a situation. NovaDel is now planning to request a meeting with FDA to discuss the development program and registration requirements for this product going forward, along with a more general discussion of the entire category of benzodiazepines, which NovaDel believes is a target-rich category for its technology. Following the completion of formulation optimization efforts, NovaDel expects to move this product into full clinical development.

HYPNOTIC (ZOLPIDEM) ORAL SPRAY

We have formulated our zolpidem oral spray and performed a pharmacokinetic study thereof during the first quarter of calendar year 2005. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. Ambien® is a registered trademark of Sanofi-Aventis. The study was designed to evaluate the pharmacokinetic profile of various doses of NovaDel s oral spray in comparison to the 10 mg Ambien® tablet. NovaDel achieved its goal of demonstrating the ability to deliver zolpidem via the oral spray technology and achieve similar blood levels faster than with the currently marketed oral tablet. In addition, although the trial was not specifically designed to assess a clinical effect of the formulation, earlier drowsiness/sedation levels were achieved using the oral spray than with an Ambien® tablet of the same dose (10 mg). The study was conducted using 10 healthy male volunteers. Each volunteer was given a 10 mg Ambien® tablet and three doses of the oral spray zolpidem --- 2.5 mg, 5 mg, and 10 mg --- in the aforementioned sequence, at weekly intervals, in the morning, in a Phase I research unit. Plasma zolpidem levels were measured and analyzed for standard pharmacokinetic parameters. In addition, drowsiness and sedation of subjects were also assessed at 15, 30 and 60 minutes following drug administration. During the first 15 minutes post-dosing, NovaDel s 10 mg oral spray formulation achieved a five-fold increase in the total amount of drug in the blood, and an eight-fold increase in the mean zolpidem concentration, when compared to the 10 mg oral tablet. Importantly from the standpoint of safety, the mean maximum plasma concentration (Cmax) and bioavailability, as measured by area-under-the-curve (AUC), achieved during the entire 12-hour observation period for the 10 mg oral spray did not exceed that of the oral tablet.

The study demonstrates a dose-response relationship. Rate of absorption, as measured by mean time to the maximum concentration level (Tmax), was faster for all three spray groups than for the oral tablet. Although not the primary objective of the study, analysis of the pharmacodynamic data indicates statistically significantly greater drowsiness/sedation levels at the earliest time-point measured (the first 15 minutes) for the 10 mg oral spray vs. the 10 mg tablet (p(less than) 0.025), which further supports the possibility that an oral spray could achieve earlier onset of action in insomnia patients when compared to the oral tablet. There was no evidence of any safety or tolerability issues. No adverse events were reported after administration of oral spray doses. None of the subjects discontinued the study. Previously published studies indicate that faster absorption of non-benzodiazepine hypnotics leads to shortened latency of sleep onset. Based on the appreciably higher AUC and concentration levels observed at the early time points, NovaDel s oral spray may have the potential to shorten Ambien s average time to onset of therapeutic action, which is reported to be approximately 30 minutes. If these observations are borne out in subsequent studies in patients with insomnia, NovaDel s zolpidem oral spray could ultimately benefit individuals who wish to achieve onset of sleep as rapidly as possible and for patients who have just ingested a meal, in which case absorption from a tablet would be even further delayed. We plan to take the oral spray version of zolpidem into full development. On August 31, 2005, the Company met with the FDA to discuss the strategy for a clinical development program that could support the submission of an NDA under the provisions of section 505(b)(2) of the Federal Food, Drug & Cosmetics Act (FFDCA).

ANTI-EMETIC (ONDANSETRON) ORAL SPRAY

We have formulated an ondansetron oral spray and performed a pharmacokinetic study thereof during the first quarter of calendar year 2005. Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GlaxoSmithKline. Zofran® is the registered trademark of GlaxoSmithKline, Inc. The study was designed to compare the pharmacokinetic profile of an 8 mg of the ondansetron oral spray to an 8 mg oral tablet of Zofran®. The study achieved its goal of demonstrating the ability to deliver ondansetron via the oral spray technology and produce a similar pharmacokinetic profile to the currently marketed oral tablet, with faster drug delivery. The study was conducted using 9 healthy male volunteers. Each volunteer was given an 8 mg Zofran® tablet and the same dose of ondansetron via oral spray at weekly intervals. Two different variations of administering the spray to the oral cavity were examined. Plasma ondansetron levels were measured and analyzed for standard pharmacokinetic parameters. The oral spray was shown to be capable of delivering ondansetron to the circulation more rapidly than the oral tablet. During the first 20 minutes post-dosing, the oral spray formulation achieved statistically significant increases in the total amount of drug delivered and in the mean ondansetron concentrations. The clinical significance of these findings remains to be confirmed in future studies. Importantly from the standpoint of safety, the mean maximum plasma concentration (C_{max}) and bioavailability, as measured by area-under-the-curve (AUC), achieved during the entire 12-hour observation period for the 8 mg oral spray, did not exceed that of the oral tablet. There was no evidence of safety or tolerability issues, and none of the subjects discontinued the study. Based on these successful results, Hana Biosciences, Inc., our licensee and co-developer of the ondansetron oral spray, intends to file an Investigational New Drug (IND) Application and to initiate a clinical development program designed to support a 505(b)(2) submission, a form of New Drug Application (NDA) that relies on data in previously approved NDAs and published literature. Hana has indicated that it is projecting a launch of the product in 2007; however, the timing of such launch, if it occurs at all, is subject to a number of risks, including those outlined in the Risk Factors Section of this Form 10-KSB. Hana may be deemed to be a related party of the Company. See Item 12, Certain Relationships and Related Transactions .

ANESTHETIC (PROPOFOL) ORAL SPRAY

We have formulated a propofol oral spray and we completed a Phase I randomized, double-blind, placebo-controlled dose-escalating study in the second quarter of calendar year 2004. Accordingly, Manhattan Pharmaceuticals, Inc. our licensee and co-developer of the propofol oral spray, has directed us to proceed with dose optimization and other formulation modifications to support full human clinical testing. In January 2005, the FDA accepted an IND, filed by Manhattan Pharmaceuticals, Inc. for the initiation of the human clinical trials required for FDA approval of propofol oral spray. The experimental product would become the first known needle-less formulation of propofol, the world s leading intravenous anesthetic, marketed as Diprivan®. Diprivan® is a registered trademark of AstraZeneca Pharmaceuticals, LP. We believe that the propofol oral spray will potentially make propofol, with its established record of safety, available for dosing in office-based and other ambulatory settings where use of an intravenous catheter is not appropriate or desirable. We believe that a propofol oral spray, in an appropriate sedative dose, has the potential to enable clinicians to better control the onset, duration and depth of sedation with high reliability and accuracy. The intended benefits of such properly timed sedation should facilitate achievement of the best procedural outcomes while avoiding unnecessary costs and anxiety. Manhattan may be deemed to be a related party of the Company. See Item 12, Certain Relationships and Related Transactions.

The Company also has identified a number of other development initiatives, but which are currently less of a priority than our six (6) priority programs. These initiatives include, among other products, clemastine, loratadine, estradiol and progesterone oral sprays.

BUSINESS DEVELOPMENT

To date, we have entered into license agreements with (i) Manhattan Pharmaceuticals, Inc., in connection with propofol, (ii) Velcera Pharmaceuticals, Inc., in connection with veterinary applications for currently marketed veterinary drugs, (iii) Par Pharmaceutical, Inc., for the marketing rights in the United States and Canada for our nitroglycerin oral aerosol, and (iv) Hana Biosciences Inc., for the marketing rights in the United States and Canada for our ondansetron oral spray. Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of NovaDel, is the Chairman and sole shareholder of Paramount BioCapital. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount BioCapital and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald and his affiliates may be deemed to beneficially own approximately 21.8% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald and his affiliates). As such, Dr. Rosenwald and Paramount BioCapital may be deemed to be our affiliates. Dr. Rosenwald and Paramount BioCapital may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences. See Item 12, Certain Relationships and Related Transactions . We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

AGREEMENT WITH MANHATTAN PHARMACEUTICALS, INC.

In April 2003, we entered into a 10-year license and development agreement with Manhattan Pharmaceuticals, Inc. 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.

LICENSE AND SUPPLY AGREEMENT WITH PAR PHARMACEUTICAL, INC.

In July 2004, we entered into a 10-year license and supply agreement with Par Pharmaceutical, Inc., a wholly owned subsidiary of Par Pharmaceutical Companies, Inc., whereby Par Pharmaceutical has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the United States 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 United States; and double-digit percentage royalties on net sales of the product in the United States and Canada. We are responsible for obtaining regulatory approval for the product and for supplying the product to Par Pharmaceutical.

AGREEMENT WITH VELCERA PHARMACEUTICALS, INC. (FORMERLY VETCO)

On September 14, 2004, we announced the granting of an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera Pharmaceuticals, Inc. (Velcera , formerly Vetco Pharmaceuticals) for development of innovative veterinary medicines. Velcera is a development-stage, privately-held animal health company headed by former senior executives at the animal units of Merial, Ltd., Merck & Co., Inc. and Schering-Plough Corporation. We received an equity stake of 529,500 shares of common stock in Velcera Pharmaceuticals, representing approximately 15% of its outstanding common stock as of October 23, 2003, along with an upfront cash technology fee of $1,500,000 (which is being recognized as income by the Company over the 20-year term of the agreement) in September 2004. The agreement, which amends an earlier agreement, provides that Velcera Pharmaceuticals shall make certain milestone payments to NovaDel 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 in our labs, at Velcera Pharmaceutical s expense, and Velcera Pharmaceuticals will fund all development and regulatory expenses. We will manufacture and supply Velcera Pharmaceuticals with the resulting pharmaceutical products. We expect our technology will help pet owners overcome the well known problem of compliance with the administration of pills to their pets. A trial conducted at an independent facility sponsored by Velcera Pharmaceuticals showed that our delivery technology was well accepted by cats and dogs. Drug development by Velcera Pharmaceuticals will focus on formulating veterinary medicines that are already being marketed.

AGREEMENT WITH HANA BIOSCIENCES, INC.

In October 2004, we entered into a 20-year license and development agreement with Hana Biosciences, Inc. Hana will develop and market the Company s oral spray version of ondansetron, the most widely prescribed anti-emetic for preventing chemotherapy-induced nausea and vomiting. Under the agreement, Hana has exclusive rights to market, sell and distribute the Company s ondansetron oral spray in the United States and Canada. We are entitled to receive milestone development payments at several junctures of development, including completion of a pharmacokinetic study, filing of an IND, FDA acceptance of the NDA and NDA approval. 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 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 s common stock during the 10 business days prior to the effective date of the agreement ($6.84 per share). In August 2005, our license and development agreement with Hana was amended to transfer the responsibility to Hana of selecting and managing a contract manufacturer who will provide clinical and commercial quantities of the ondansetron oral spray product.

BUSINESS STRATEGY

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 will enhance the performance of the active ingredient and potentially fulfill an unmet medical need for the patient. In June 2005, the Company received an approvable letter for Nitroglycerin Lingual Aerosol. For the remaining five priority product candidates in NovaDel s pipeline, the Company has completed pilot pharmacokinetic studies. 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 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 could have a material adverse effect on our operations.

In addition to the current six priority product candidates, the Company intends to continue to identify and pursue additional product candidates for development. We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

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.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we intend to develop some such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. Our lack of working capital has impaired our ability to pursue such strategy. See Item 6 Management s Discussion and Analysis or Plan of Operation.

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 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. We believe that this delivery system may offer certain advantages, including more rapid delivery of drugs to the bloodstream, improving the safety profile of certain drugs by lowering the required dosage to be administered, improving dose reliability, allowing medication to be taken without water and improved patient convenience and compliance. Drug absorption through the mucosal membranes of the mouth is rapid and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

PROPOSED PRODUCTS

Our proposed products are subjected to laboratory testing and stability studies and tested for therapeutic comparison to the originators products by qualified laboratories and clinics. To the extent that two drug products with the same active ingredients are substantially identical in terms of their rate and extent of absorption in the human body (bioavailability), they are considered bioequivalent. If the accumulated data demonstrates bioequivalency, submission is then made to the FDA (through the filing of an Abbreviated New Drug Application (ANDA)) for its review and approval to manufacture and market. If the accumulated data demonstrates that there are differences in the two drugs rate and extent of absorption into the human body, or if it is intended to make additional or different claims regarding therapeutic effect for the newly developed product, submission is made to the FDA via an NDA for its review and approval under Section 505(b)(1) or Section 505(b)(2) of the FFDCA. An NDA submitted under Section 505(b)(2) of the FFDCA, is generally less complex than an ordinary Section 505(b)(1) NDA. We expect that the majority of our products in development will require the filing of Section 505(b)(2) NDA s because, although such products are known chemical entities, we or our licensees may be making new claims as to therapeutic effects or lessened side effects, or both.

We estimate that development of the Company s new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes two to three years for the Section 505(b)(2) NDA or ANDA Section 505(j) process. Development of products requiring additional clinical studies under full NDA s, may take four to seven years. Our determination regarding the availability of ANDA s or Section 505(b)(2) NDA s for our products under development may not be accurate and pre-marketing approval for our proposed products might not be obtained on a timely basis, if at all. See Item 1, Description of Business - Government Regulation.

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 proposed products, 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 products. We intend to position our proposed products 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 proposed products.

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 proposed proprietary products, 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 both internalize and contract out the manufacturing of our proposed products. We currently have a pilot manufacturing facility at one of our present locations which we believe is adequate for our needs with respect to our requirements for formulation development, stability testing and clinical supplies. The lease on this older facility expires in December 2005. We have also leased a new, larger facility, which will have adequate space for our future foreseeable requirements for production, manufacturing and warehouse space. We began to occupy this new space during the third quarter of calendar year 2003. This new facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices (cGMP), and would require additional investment in order to attain that capability. After the expiration of the lease on the older facility, the Company will have to contract out manufacturing and/or invest additional funds in the new facility in order to provide internal manufacturing capability. The manufacture of our pharmaceutical products 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, Description of Business - Government Regulation and - Raw Materials and Suppliers.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX USA, Ltd. (INyX), whereby INyX will manufacture and supply the Company s 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 the Company 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. The Company had total fixed assets of $570,000 and inventories of $549,000 at the facilities of INyX as of July 31, 2005. Such assets are the property of the Company and cannot be used by INyX for any other business. In the event that the Company s contract with INyX is terminated for any reason, such assets are to be returned to the Company.

RAW MATERIALS AND SUPPLIERS

We believe that the active ingredients used in the manufacture of our proposed pharmaceutical products are presently available from numerous suppliers located in the United States, 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 proposed products. 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 cost (which will, in turn, have an impact on the cost of our proposed products). To the extent that transactions relating to the purchase of raw materials involve currencies other than United States 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 oral spray products 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 pharmaceutical 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 specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

GOVERNMENT REGULATION

The development, manufacture and commercialization of pharmaceutical products are generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, 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 FFDCA, a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA.

The FDA approval process relating to a new drug differs, 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, including complete reports of pre-clinical, clinical and laboratory studies to prove such product s safety, quality and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA based on published safety and efficacy studies conducted by others may also be required to be submitted for a drug product with a previously approved active ingredient, if the method of delivery, strength or dosage is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process.

While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug.

The NDA approval process generally requires between 10 to 24 months from NDA submission to pre-marketing approval, although in the case of an NDA submitted pursuant to Section 505(b)(2) of the FFDCA this time frame may be significantly shorter. We believe that most products developed in oral spray delivery systems (dosage forms) usually will require submission of an NDA under Section 505(b)(2). This is because the safety and efficacy of the drug compound used in the oral spray formulation generally can be established in previous trials in NDA submissions and publications.

We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes four to seven years for the NDA process, although NDA s submitted under Section 505(b)(2) of the FFDCA are generally less complex than an ordinary NDA and may be acted upon by the FDA in a shorter period of time. Our determinations regarding the availability of ANDA s for our proposed products may not be accurate and pre-marketing approval for our proposed products might not be obtained on a timely basis, if at all. The FDA application procedure has become more rigorous and costly and the FDA currently performs pre-approval and periodic inspections of each finished dosage form and each active ingredient.

The manufacture of our pharmaceutical products will be subject to cGMP prescribed by the FDA, pre-approval inspection by the FDA before beginning commercial manufacture of such products and periodic cGMP compliance inspections by the FDA thereafter.

COMPETITION

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

We are aware of several companies that are selling or developing oral spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oralspray which is in an air propelled dispensing system (our nitroglycerin lingual spray is in a propellant based dispensing system).

Nitrolingual® is a registered trademark of First Horizon Pharmaceutical Corp. Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via their RapidMist device. RapidMist is a pending trademark of Generex Biotechnology Corp. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the United Kingdom, 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 (MS) and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Arakis Ltd., based in the United Kingdom, also claims to be developing an analgesic to be delivered suborally via a non-pressurized metered dose spray formulation.

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 United States 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. Five United States patents and six European patents have been issued and other applications are pending. 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 United States Patent and Trademark Office (USPTO) with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty (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, respectively, 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, benzediasepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the United Kingdom, 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 issued a Notice of Allowance on April 21, 2005. 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, benzo-diazepams, 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 (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 United Kingdom, 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. We have received a further Office Action from the Canadian Patent Office and have filed a responsive communication thereto.

BUCCAL NONPOLAR SPRAY FOR NITROGLYCERIN. On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

On February 21, 1997, we filed a PCT application (PCT 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 an Office Action to us dated July 21, 2004. We are in the process of responding to such Office Action.

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 United Kingdom, 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 United States, 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 United States 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 are in the process of responding 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.

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. We are currently prosecuting these applications.

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 United States, 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 October 1, 2005, we had 26 total employees, all of whom were full-time employees.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange 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 or contact Michael Spicer, our Chief Financial Officer at our address as set forth above 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-KSB.

ITEM 2. DESCRIPTION OF PROPERTY.

Our executive offices, laboratory, and warehousing space are located at 25 Minneakoning Road, Flemington, New Jersey (the new facility). The facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease, expiring in August 2013. Presently, we are only occupying a portion of our space in the building. We also have approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey (the old facility), which also formerly housed our executive offices. We occupy that space under a five-year lease expiring in December 2005. During fiscal 2005, we paid rent for both facilities of approximately $521,000 including real estate taxes. This new facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices (cGMP), and would require additional investment in order to attain that capability. After the expiration of the lease on the old facility, the Company will have to contract out manufacturing and/or invest additional funds in the new facility in order to provide internal manufacturing capability. The manufacture of our pharmaceutical products 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, Description of Business - Government Regulation and Raw Materials and Suppliers.

ITEM 3. LEGAL PROCEEDINGS.

There are no legal proceedings to which we are a party and we are not aware of any contemplated proceedings by a governmental authority.

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

During the fourth quarter of fiscal year 2005, no matters were submitted to a vote of security holders, through the solicitation of proxies or otherwise.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

(A) MARKET INFORMATION. Since May 11, 2004, our common stock has been traded on the American Stock Exchange under the ticker symbol NVD . Prior thereto, our common stock was traded in the over-the-counter market on the OTC Bulletin Board under the ticker symbol NVDL . The following table sets forth the range of high and low closing sales prices of our common stock as reported by the AMEX and the OTC Bulletin Board for each fiscal quarter for the past two fiscal years. For the period of time that our common stock was traded in the over-the-counter market on the OTC Bulletin Board, such prices reflect inter-dealer prices, without retail mark-up, mark-down, or commission and may not represent actual transactions.

	CLOSING SALE PRICES ($)	
	HIGH	LOW
FISCAL 2005		
First Quarter (August 1, 2004 through October 31, 2004)	1.95	1.28
Second Quarter (November 1, 2004 through January 31, 2005)	1.65	1.40
Third Quarter (February 1, 2005 through April 30, 2005)	1.48	1.12
Fourth Quarter (May 1, 2005 through July 31, 2005)	1.39	1.09
FISCAL 2004		
First Quarter (August 1, 2003 through October 31, 2003)	2.45	1.54
Second Quarter (November 1, 2003 through January 31, 2004)	1.99	1.29
Third Quarter (February 1, 2004 through April 30, 2004)	2.23	1.43
Fourth Quarter (May 1, 2004 through July 31, 2004)	2.45	1.35

(B) HOLDERS. As of October 1, 2005 there were approximately 141 record holders of our common stock.

(C) DIVIDENDS. 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.

ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

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

GENERAL

We are engaged in the development of novel application drug delivery systems for presently marketed prescription, and veterinary drugs. Our patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and greatly accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on making it available for drugs that are already available and proven in the marketplace.

Since its inception, substantially all of the Company s revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. Although substantially all of the Company s revenues to date have been derived from its consulting business, the future growth and profitability of the Company will be principally dependent upon its ability to successfully develop its products and to market and distribute the final products either internally or with the assistance of a strategic partner.

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Recent 2005 highlights include the following product development and business achievements:

Entered into two new strategic alliances:

- License agreement with Hana Biosciences: In October 2004, we entered into a 20-year license and development agreement with Hana Biosciences, Inc. Hana will develop and market the Company s oral spray version of ondansetron, the most widely prescribed anti-emetic for preventing chemotherapy-induced nausea and vomiting.
- License agreement with Velcera Pharmaceuticals: In September 2004, we granted an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera Pharmaceuticals, Inc. for development of innovative veterinary medicines.

Completed three human proof of concept PK studies, including studies for (i) zolpidem (Ambien®); (ii) ondansetron (Zofran®); and (iii) alprazolam (Xanax®).

Received FDA approvable letter for our NitroMist NDA.

Completed three pre-IND meetings with the FDA, including meetings for the following product candidates: (i) sumatriptan (Imitrex®); (ii) zolpidem (Ambien®); and (iii) ondansetron (Zofran®).

Completed a financing with approximately $6.3 million of net proceeds.

Addition of Chief Financial Officer.

Over the next fiscal year, the Company expects to continue to stay focused on its six priority products: nitroglycerin, sumatriptan, ondansetron, zolpidem, alprazolam and propofol.

Nitroglycerin. On June 1, 2005, the Company received an approvable letter from the FDA regarding its NDA for NitroMist (nitroglycerin lingual aerosol). The Company believes that the FDA is likely to give final approval once the Company completes its previously agreed-to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval.

Sumatriptan. The Company had a pre-IND meeting with the FDA on August 10, 2005, and anticipates filing the IND during the second half of calendar year 2005. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the sumatriptan oral spray product.

Zolpidem. The Company had a pre-IND meeting with the FDA on August 31, 2005 and anticipates filing the IND during the first quarter of calendar year 2006. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the zolpidem oral spray product.

Ondansetron. The Company s partner for this product, Hana Biosciences, had a pre-IND meeting with the FDA on September 1, 2005 and anticipates filing the IND during the second half of calendar year 2005. Subsequent to the IND submission, Hana plans to execute the clinical protocol and administer clinical trials for the ondansetron oral spray product.

Alprazolam. The Company plans to request a pre-IND meeting with the FDA with an anticipated goal of filing the IND during the first half of calendar year 2006. Subsequent to the IND submission, the Company plans to execute the clinical protocol and administer clinical trials for the alprazolam oral spray product.

Propofol. We continue to support our partner, Manhattan Pharmaceuticals, who has filed an IND with the FDA. Manhattan Pharmaceuticals will oversee all clinical development and regulatory approval for this product.

Our veterinary initiatives are being carried out with our partner, Velcera Pharmaceuticals. In April 2005, the first designated compound was determined. NovaDel has commenced formulation of this designated compound.

The Company plans to hire additional employees in the laboratory to support our research and development efforts going forward; however, we do not believe that a significant number of new employees will be required in the next 12 months.

RESULTS OF OPERATIONS

FISCAL YEAR 2005 COMPARED TO FISCAL YEAR 2004

License fees and milestone payments increased to $141,000 in fiscal 2005 from $13,000 in fiscal 2004 primarily due to the signing of new partnership agreements with Hana and Velcera in the first quarter of fiscal 2005.

Consulting revenues for fiscal 2005 decreased to $298,000 in fiscal 2005 from $453,000 in fiscal 2004 primarily as a result of lower revenue from our arrangement with Manhattan, partially offset by revenue associated with the Company s arrangement with Velcera.

Research and development expenses increased approximately $1,334,000 to $3,826,000 from $2,492,000 for fiscal 2004. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The increase in research and development expenses is primarily related to the following items:

- Approximate $264,000 increase, primarily related to pharmacokinetic studies completed in fiscal 2005 for three of the Company s priority product candidates, including (i) zolpidem (Ambien®); (ii) ondansetron (Zofran®) and (iii) alprazolam (Xanax®)
- Approximate $670,000 increase, primarily related to outsourced manufacturing fees associated with process validation and method transfer activities for the Company s NitroMist product candidate
- Approximate $630,000 increase due to higher payroll and allocated facility and administrative costs, primarily as a result of an increase in R&D-related personnel in fiscal 2005
- Approximate $185,000 decrease in R&D-related consultants expense

Consulting, selling, general and administrative expenses increased approximately $1,764,000 to $6,391,000 from $4,627,000 for fiscal 2004. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The increase in consulting, selling, general and administrative costs is primarily related to the following items:

- Approximate $297,000 increase in outside legal costs, primarily related to the filing of additional patent applications in fiscal 2005
- Approximate $629,000 increase in compensation expense related to variable accounting for stock options. In fiscal 2005 the Company recognized a credit of $106,000, as compared to a credit of $736,000 in fiscal 2004. The decrease in the credit is primarily attributable to a significant reduction in fiscal 2005 of the number of stock options that are subject to variable accounting
- $307,000 non-cash charge to consultants expense in fiscal 2005 for restricted shares of the Company s common stock awarded to a consultant
- The remaining increase, net of individually offsetting items of lesser significance, is primarily attributable to higher payroll, recruiting and relocation expenses as a result of hiring additional employees.

Primarily as a result of the factors described above, total costs and expenses for fiscal 2005 increased approximately $3,098,000 to approximately $10,217,000 from $7,119,000 for fiscal 2004.

Interest income decreased approximately $11,000 to $87,000 for fiscal 2005 from $98,000 for fiscal 2004 due to lower average cash and investment balances.

Income tax benefit for fiscal 2005 was approximately $241,000 compared to approximately $214,000 for fiscal 2004. These benefits resulted from the sale of the Company s New Jersey net operating losses.

The resulting net loss for fiscal 2005 was $9,450,000 compared to a net loss of $6,341,000 for fiscal 2004.

LIQUIDITY AND CAPITAL RESOURCES

From its inception, the Company s principal sources of capital were consulting revenues, private placements and a public offering of its securities, as well as loans and capital contributions from the Company s principal stockholders. The Company has had a history of recurring losses from operations, giving rise to an accumulated deficit at July 31, 2005 of $34,391,000. At July 31, 2005, we had working capital of approximately $6,781,000 as compared to working capital of $7,676,000 at July 31, 2004, representing a net decrease in working capital of approximately $895,000. During fiscal 2005, the Company successfully closed an offering of its common stock and warrants to purchase shares of its common stock (Private Placement).

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The Private Placement involved the sale of approximately 6,733,024 shares of common stock, and warrants to purchase 2,356,559 shares of common stock. The Company received proceeds, net of offering costs, of approximately $6,309,000.

Net cash used in operating activities was approximately $6,258,000 for fiscal 2005 compared to net cash used in operating activities of approximately $6,120,000 for fiscal 2004. Net cash used in operating activities for both fiscal 2005 and fiscal 2004 was primarily attributable to the net loss of $9,450,000 and $6,341,000, respectively, partially offset by an increase in deferred revenue in fiscal 2005 and 2004 of $1,974,000 and $362,000, respectively, and increased by an adjustment to eliminate a noncash benefit from variable plan accounting in fiscal 2005 and 2004 of $106,000 and $736,000, respectively. The increase in deferred revenue is attributable to payments received by the Company from its licensees, which payments are being amortized over the remaining terms of the agreements with the licensees. Also impacting net cash used in operating activities in fiscal 2005 is the $549,000 increase in inventory related to the purchase of raw materials for the Company s nitroglycerin lingual spray product candidate; and a $938,000 increase in accounts payable primarily related to costs incurred in conjunction with the manufacturing and process development of the Company s nitroglycerin lingual spray product candidate.

In fiscal 2005, $1,670,000 was provided from investing activities, principally from the sales and maturities of investments, net of purchases of investments, which amounts exceeded capital expenditures. In fiscal 2004, $8,005,000 was used in investing activities which primarily related to the purchase of investments, net of maturities of investments. Capital expenditures for fiscal 2005 totaled approximately $2,305,000 and consisted primarily of $1,295,000 in leasehold improvements for the Company s new laboratory facility and $570,000 in manufacturing equipment at INyX for the manufacture of the Company s product candidate. The Company anticipates that its new laboratory facility will be completed by the end of calendar 2005, and that such efforts will not require significant additional capital.

Cash provided by financing activities decreased approximately $6,103,000 in fiscal 2005 to $7,102,000 as compared to $13,205,000 in fiscal 2004 primarily as a result of a decrease in proceeds received by the Company for the issuance of common stock in conjunction with a private placement.

Until and unless the Company s operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and short-term investments, and through the sources of capital described below. The Company s long-term liquidity is contingent upon achieving product sales and/or obtaining additional financing. The most likely sources of financing include private placements of its equity or debt securities or bridge loans to the Company from third-party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Although we expect to have sufficient cash to fund our operations through fiscal 2006, we would have to significantly reduce the pace of our ongoing development of our six priority product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our six priority product candidates, we estimate that we will need to raise additional capital during fiscal year 2006 in order to fully fund our development activities through July 31, 2006. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. If we are unable to raise additional capital in fiscal 2006, we will likely be forced to curtail our desired development activities, which will delay the development of our product candidates. There can be no assurance that such capital will be available to us on favorable terms or at all. We will need additional financing thereafter until we achieve profitability, if ever.

CRITICAL ACCOUNTING POLICIES

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

REVENUE RECOGNITION - Revenue is recognized as earned. Invoices, for client project costs, are created and presented at the end of each month, for that month. Accounts receivable reflects these invoices at the end of the month in which the invoice was created. Consulting revenues from contract clinical research are recognized as earned. The Company also receives milestone and upfront payments which are initially deferred and subsequently amortized into revenue over the contractual period.

STOCK-BASED COMPENSATION - The Company has been using the intrinsic value method prescribed by APB Opinion No. 25, rather than the fair value method provided for under FAS 123, to measure compensation expense for options granted to employees.

As a result of cashless exercise provisions in its employee stock option agreements, the Company has used variable accounting treatment under the Financial Accounting Standards Board s Interpretation 44, for issued and outstanding stock options since January 2002. On October 20, 2004, the Board of Directors of the Company rescinded the Company s cashless exercise provision for all of the Company s outstanding option grants. As a result, variable accounting is not required to be applied to all option grants. Variable plan accounting is still required for approximately 310,000 outstanding options of the Company, for which option exercise prices were modified from the original agreements. These option agreements will continue to be accounted for under variable plan accounting until such time as they lapse or are exercised.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses are expensed as incurred.

OFF-BALANCE SHEET ARRANGEMENTS

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

INFLATION

The Company does not believe that inflation has had a material effect on its results of operations during the past three fiscal years. There can be no assurance that the Company s business will not be affected by inflation in the future.

RECENT ACCOUNTING PRONOUNCEMENT

In December 2004, the FASB issued SFAS No. 123R (revised 2004), Share-Based Payment (SFAS 123R), which amends SFAS No. 123, Accounting for Stock-Based Compensation, (SFAS 123) and will be effective for the Company beginning with the fiscal quarter ending October 31, 2005. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is in the process of determining the method of adoption and is evaluating the effect that the adoption will have on its financial position and results of operations, although the Company believes such adoption will increase recorded compensation expense in the future.

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 and elsewhere in this report and in any documents incorporated in this report by reference.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

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. 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 FDA approval and achieve market acceptance of our proposed products and respond to competition.

We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of July 31, 2005 of approximately $34.4 million. We incurred losses in each of our last nine fiscal years, including a net loss of approximately $9.5 million for the fiscal year ended July 31, 2005. Because we increased our product development activities, 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 proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

The research, development, testing and approval of our proposed products involve significant expenditures, and accordingly, we require significant capital to fund such expenditures. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new products) that we will need to raise additional capital in fiscal 2006, likely by selling shares of our capital stock and other securities. 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. We will require significant additional financing and/or a strategic alliance with a well-funded development partner to aggressively pursue our business plan. We have no current arrangements with respect to, or sources of, additional financing, and additional financing may not be available to us on acceptable terms, if at all. Unless we raise additional financing, we may not have sufficient funds and we may not be able to complete development and commercialization of our proposed products or continue operating. See Item 12, Certain Relationships and Related Transactions .

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 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 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 100,000,000 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. See Risk Factors - Additional Authorized Shares Of Common Stock And Preferred Stock Available For Issuance May Adversely Affect The Market for a description of certain rights of Paramount BioCapital that may negatively impact our ability to raise additional capital.

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 will greatly enhance speed of onset of therapeutic effect, 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.

We filed an NDA for our nitroglycerin lingual spray, NitroMist , on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act (PDUFA) date of June 4, 2005, for NitroMist , and received an approvable letter from the FDA on June 2, 2005. We believe that the FDA is likely give final approval of NitroMist once we complete certain manufacturing process validation commitments which we had previously agreed to with the FDA. The FDA is not requiring us to complete any additional clinical studies for approval. Although we currently intend to complete the manufacturing process validation commitments, the FDA may not grant us final marketing approval for NitroMist if we do not timely complete the manufacturing process validation commitments or for other reasons. NitroMist is a trademark of Par Pharmaceuticals, Inc.

We have initiated and completed pharmacokinetic studies of our priority products during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, alprazolam, propofol and zolpidem. 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 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 and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on loratadine, clemastine, estradiol and progesterone has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds.

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 NovaDel, is the Chairman and sole shareholder of Paramount BioCapital. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount BioCapital and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald and his affiliates may be deemed to beneficially own approximately 21.8% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald and his affiliates). As such, Dr. Rosenwald and Paramount BioCapital may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on the Company s Board of Directors. He has not exercised such right; however, he may do so in the future. Dr. Rosenwald and Paramount BioCapital may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences. 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 BioCapital, 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 nor Paramount BioCapital, 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. See We Will Require Significant Capital For Product Development and Commercialization . In connection with any future offering by the Company of its debt or equity securities for gross proceeds of greater than $1 million that is intended to be exempt from Section 5 of the Securities Act on or before May 27, 2006, the Company has granted Paramount Biocapital, Inc. (Paramount) the right of first refusal to act as a placement agent or co-agent. Prior to engaging in any such offering, the Company must offer Paramount the opportunity to match the terms, conditions and limitations of any such proposed future private offering (including, but not limited to, cash fees and placement warrant coverage, if any; offering price of securities, including warrants, if any, as well as any applicable warrant exercise price and percentage of warrant coverage ; and the quality and suitability of any proposed investors as shareholders of the Company). Should Paramount be unwilling to match or propose superior terms, conditions and limitations than those offered by an alternate placement agent, the Company may engage the alternate placement agent as its exclusive placement agent, investment banker, finder or broker-dealer, as applicable, and Paramount will have no right to participate in the subsequent private offering.

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Should Paramount match or propose superior terms, conditions and limitations than those originally proposed by the alternate placement agent, after providing the alternate placement agent with the opportunity to match Paramount s offer, then either (i) Paramount and the alternate placement agent will each be allowed to participate in equal amounts toward the final total capital raise, as co-agents, or (ii) Paramount will be engaged by the Company to act as the exclusive placement agent for the subsequent private offering. The Board of Directors of the Company, at its sole discretion, will make the final and binding determination as to whether proposals are equal, substantially similar or superior to each other.

Our former outside securities counsel, Dickstein Shapiro Morin & Oshinsky LLP, who represented us in the private placement completed on May 26, 2005, also represents Dr. Rosenwald, Paramount BioCapital and certain of their affiliates from time to time, for which it has received, and will receive, customary fees and reimbursement of expenses. Dickstein Shapiro Morin & Oshinsky LLP continues to represent the Company with respect to its intellectual property matters.

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 successfully to raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our proposed products. 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 proposed products 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. See Risk Factors - We Will Require Significant Capital For Product Development And Commercialization And - Our Strategy Is To Enter Into Collaboration Agreements With Third Parties 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 .

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until the second calendar quarter of 2006 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. Any one or more of our proposed proprietary products 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 products to achieve commercial viability would have a material adverse effect on us.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our proposed products 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 products must be obtained before the proposed products will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps in calendar year 2006 or thereafter. 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 proposed products or develop such proposed products on a timely basis. Further, such proposed products 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 proposed product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

We have no experience in marketing or distribution at the consumer level of our proposed products. 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 Pharmaceutical, Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our proposed products. 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 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 (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 proposed products. 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 proposed pharmaceutical products are presently available from numerous suppliers located in the United States, 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 proposed products, 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, who intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. 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 or INyX 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.

OUR INTERNAL CONTROLS AND PROCEDURES HAVE BEEN MATERIALLY DEFICIENT, AND WE ARE BEGINNING THE PROCESS OF CORRECTING INTERNAL CONTROL DEFICIENCIES.

In October 2004, we and our independent registered public accounting firm recognized that our internal controls had material weaknesses. These material weaknesses led in part to the delay in the production of our audited financial statements for fiscal 2004.

We have restated our results of operations for the fiscal years ended July 31, 2002, and July 31, 2003, and for our quarterly results in fiscal years 2004, 2003 and 2002. Our independent registered public accounting firm advised us of material weaknesses noted during its audit of our 2004 financial statements.

If we cannot rectify these material weaknesses through remedial measures and improvements to our systems and procedures, management may encounter difficulties in timely assessing business performance and identifying incipient strategic and oversight issues. In December 2004, we hired a new Chief Financial Officer and in March 2005, we hired a Corporate Controller. We believe that these hirings have improved and will continue to improve our internal controls, particularly with respect to our need to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

We will apply resources at all relevant managerial levels toward the task of improving our internal control environment. We cannot provide assurances as to the timing of the completion of these efforts or estimates of the prospective costs of these efforts, either in dollar terms or in the form of management attention. We cannot be certain that the measures we take will ensure that we implement and maintain adequate internal controls in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT 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 could be harmed.

We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. 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 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. 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 stock 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 and American Stock Exchange (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 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 will require 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 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 dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

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

We are aware of several companies that are selling or developing oral spray products. 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. 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 is listed as the assignee on 15 United States patents. RapidMist is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the United Kingdom, 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 (MS) and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Arakis Ltd., based in the United Kingdom, also claims to be developing an analgesic to be delivered suborally via a non-pressurized metered dose spray formulation.

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 proposed products, 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 proposed products, 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 United States 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 (the FFDCA), as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product s safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND, pursuant to which permission is sought to begin preliminary clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug. We believe that the products we develop in spray dosage form will require the submission of an NDA, which may be based upon published safety and efficacy studies conducted by others, which is referred to as a 505(b)(2) NDA. We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes two to three years for 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 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 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. On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol), indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The Company believes that the FDA will give final approval once the Company completes its previously agreed to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. NitroMist is a pending trademark of Par Pharmaceutical Companies, Inc.

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 United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States 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 United States 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 IS TO ENTER INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES 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 our proposed products and for the manufacturing, marketing and commercialization of such products depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products. We have entered into a license agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation; an exclusive worldwide license for our proprietary oral spray technology with Velcera Pharmaceuticals for the development of innovative veterinary medicines pursuant to which we are entitled to milestone payments for each product developed by Velcera and royalties on product sales and Velcera will fund all development and regulatory expenses; a license and supply agreement with Par Pharmaceutical pursuant to which Par Pharmaceutical has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the United States and Canada; and a license agreement with Hana Biosciences for the marketing rights in the United States and Canada for our ondansetron oral spray. 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 our 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 the products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, 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 United States 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 United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office 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.

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 United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office 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. We currently have five patents issued in the United States and six patents issued outside of the United States. In addition, we have approximately 120 patents pending worldwide. Our pending patent applications, those we may file in the future and those we may license from third parties may not result in the United States Patent and Trademark Office 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 United States Patent and Trademark Office 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 products and processes in the United States 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 United States Patent and Trademark Office keeps United States 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.

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 would 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 would 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.

On September 6, 2005, the Board of Directors of the Company announced that they would not be renewing the employment contract of Dr. Shangold. Accordingly, Dr. Shangold will cease to be the President and Chief Executive Officer of the Company on December 22, 2005.

On September 2, 2005, the Board elected Robert G. Savage, a current Director and a highly experienced professional in the pharmaceutical industry, as non-executive Chairman of the Board. Mr. Savage will continue to serve as a member of the Audit Committee and the Corporate Governance and Nominating Committee of the Board. On October 19, 2005, the Board of Directors appointed William F. Hamilton as Chairman of the Corporate Governance and Nominating Committee. There was no arrangement or understanding between Mr. Savage and any other persons pursuant to which Mr. Savage was elected non-executive Chairman of the Board of Directors and there are no related party transactions between Mr. Savage and the Company.

On September 28, 2005, the Board announced its appointment of Dr. Jan H. Egberts as the Company s Chief Operating Officer, effective September 26, 2005, reporting to the Chairman of the Board. Dr. Egberts will assume the positions of President and Chief Executive Officer of the Company on December 23, 2005. There was no arrangement or understanding between Dr. Egberts and any other persons pursuant to which Dr. Egberts was elected Chief Operating Officer and there are no related party transactions between Dr. Egberts and the Company.

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.

We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

WE ARE CONTROLLED 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. Management and our affiliates currently beneficially own (including shares they have the right to acquire) greater than 30% of the common stock on a fully-diluted basis. 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. Moreover, Dr. Rosenwald has the ability to designate an individual to serve on the Company s Board of Directors. He has not exercised such right; however, he may do so in the future. Such positions may discourage or prevent any proposed takeover of NovaDel, 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 the 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 the 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 United States 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.

Our common stock has been listed for quotation on the AMEX since May 11, 2004. Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the 12-month period ended July 31, 2005, the closing price of our common stock has ranged from $1.09 to $1.95. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended July 31, 2005, the average daily trading volume in our common stock was approximately 42,088 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 addition, our earnings and losses may be volatile because of our need to account for compensation expense on a variable accounting basis on certain of our outstanding stock options. The impact on our earnings and losses because of such expense will vary in relation to the volatility of our stock price. On October 20, 2004, our Board of Directors rescinded the cashless exercise provision for all of our outstanding option grants. As a result, we are no longer required to apply variable accounting to all of our option grants; however, variable option accounting may still be

required for certain option grants, as disclosed in the financial statements included in this Annual Report.

In addition, we may not be able to continue to adhere to the strict listing criteria of the AMEX. 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. 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.

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

The Commission 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 Commission 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 Commission, 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 100,000,000 shares of common stock. As of October 1, 2005, there were 40,597,318 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 July 31, 2005, we had outstanding stock options and warrants to purchase approximately 28,235,000 shares of common stock, the exercise price of which range between $0.46 per share to $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. Of the reserved shares, a total of 4,400,000 shares are currently reserved for issuance in connection with our 1992, 1997 and 1998 Stock Option Plans, respectively, of which options to purchase an aggregate of 500,000, 500,000 and 3,125,500, shares have been issued under the respective stock option plans. Another 4,050,000 shares are reserved for issuance and available for the non-plan options granted pursuant to the terms of the employment agreements of various of our current and former officers. 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 . 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 of Directors. 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 of Directors 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, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year 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 two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

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

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

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

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

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

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

In 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 2,693,209 shares of our Common Stock. The sales of the shares of Common Stock and warrants resulted in gross proceeds to the Company of $7.1 million, prior to offering expenses. The resale of our Common Stock and the exercise of the warrants described immediately above in this risk factor are subject to a currently effective registration statement filed by the Company on Form 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 the Company and the industry in which we participate
- 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.

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 an 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 an agreement 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 a registration statement was declared effective on 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 7. FINANCIAL STATEMENTS.

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

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 8A. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures

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

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of July 31, 2005, the end of the period covered by this Annual Report on Form 10-KSB. Based on this evaluation, the Company s Chief Executive Officer and its Chief Financial Officer concluded that as of the end of the period covered by this report, the Company s disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

The Company s management, including its Chief Executive Officer and its Chief Financial Officer, does not expect that disclosure controls or internal controls over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

(b) Changes in Internal Controls

During the fourth quarter of fiscal 2005, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION.

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

The names and ages of our Directors and Executive Officers 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, with the exception of Dr. El-Shafy, the following individuals are the Executive Officers of the Company: Dr. Shangold, Mr. Cohen, Dr. Egberts, Ms. Frydman, Dr. Kwan and Mr. Spicer.

NAME	AGE	POSITION WITH THE COMPANY
Thomas E. Bonney	40	Director
William F. Hamilton, Ph.D.	66	Director
Lawrence J. Kessel, M.D. FACP	52	Director
Charles Nemeroff, M.D., Ph.D.	56	Director
Mark H. Rachesky, M.D.	46	Director
Robert G. Savage	52	Director
Gary A. Shangold, M.D.	52	President, Chief Executive Officer and Director
Barry C. Cohen	43	Vice President, Business and New Product Development
Jan H. Egberts, M.D.	47	Chief Operating Officer
Jean W. Frydman	52	Vice President, General Counsel and Corporate Secretary
Henry Kwan, Ph.D.	55	Head of Pharmaceutical Sciences
Michael E. Spicer	52	Chief Financial Officer

THOMAS E. BONNEY, Director. Mr. Bonney was elected to the Board of Directors in March 2005. From 2002 to the present, Mr. Bonney has been President of CMF Associates, LLC, a financial consulting firm. 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. He is a member and chair of our Audit Committee.

WILLIAM F. HAMILTON, Ph.D., Director. Dr. Hamilton was elected to the Board of Directors in March 2003. 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 a member of the Audit Committee, and Compensation Committee and chair of our Corporate Governance and Nominating Committee.

LAWRENCE JAY KESSEL, M.D., FACP, Director. Dr. Kessel was elected to the Board of Directors in March 2003. Dr. Kessel, a physician, is President of Lawrence J. Kessel, M.D., & Associates, PC, a four-physician practice specializing in Internal Medicine and Geriatrics since 1984. He is an active staff attending and Clinical Instructor at Chestnut Hill Hospital (University of Pennsylvania affiliate) and Roxborough Memorial Hospital in Philadelphia, Pennsylvania. Dr. Kessel is a Board Reviewer for the American Board of Internal Medicine, as well as a Fellow of the American College of Physicians. He also serves on the advisory board of Independence Blue Cross and is a Clinical Assistant Professor in the Department of Medicine at Temple University Medical School. Dr. Kessel presently serves as a director of Keryx Biopharmaceuticals, Inc., a publicly-traded company specializing in novel pharmaceutical products for the treatment of serious, life-threatening diseases. Dr. Kessel serves on the Biotherapeutic Scientific Advisory Board of DOR BioPharma Inc., a publicly-traded company focused on development of therapeutic products and biomedical countermeasures for areas of unmet medical needs and the Scientific Advisory Board of Cypress Biosciences Inc., a publicly-traded pharmaceutical company specializing in the treatment of central nervous system disorders. He is a member and chair of our Compensation Committee and a member of our Corporate Governance and Nominating Committee.

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CHARLES NEMEROFF, M.D., Ph.D., Director. Dr. Nemeroff was elected to the Board of Directors in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the 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, Organon, Glaxo-SmithKline Beecham and Wyeth-Ayerst, and is a clinical advisor to Acadia Pharmaceutical. In 2002, he was elected to the Institute of Medicine. He is a member of the Compensation Committee.

MARK H. RACHESKY, M.D., Director. Dr. Rachesky joined the Board of Directors in June 2003. Since 1996 Dr. Rachesky has been the President of MHR Fund Management LLC and affiliates, investment managers of various private investment funds that invest in inefficient market sectors, including special situation equities and distressed investments. Dr. Rachesky is currently on the board of directors of Neose Technologies, Inc., a publicly-traded company developing a drug manufacturing process and proprietary drugs, Emisphere Technologies, Inc., a publicly-traded company pioneering the oral delivery of otherwise injectable drugs and is Chairman of the Board of Leap Wireless International Inc., a publicly-traded company that provides innovative, wireless, communications services for the mass market.

ROBERT G. SAVAGE, M.B.A., Non-Executive Chairman of the Board. Mr. Savage was elected to the Board of Directors in February 2004, and was elected to the position of Non-Executive Chairman of the Board on September 2, 2005. Since May 2003, Mr. Savage has served as President of Strategic Imagery LLC, a consulting company he founded. From February 2002 to April 2003, Mr. Savage was Group Vice President and President for the General Therapeutics and Inflammation Business of Pharmacia Corporation, a research-based pharmaceutical firm acquired by Pfizer Inc. in April 2003. From September 1996 to January 2002, Mr. Savage held several senior positions with Johnson & Johnson, including Worldwide Chairman for the Pharmaceuticals Group during 2001, Company Group Chairman responsible for the North America pharmaceuticals business from 2000 to 2001, President, Ortho-McNeil Pharmaceuticals, from 1998 to 2000 and Vice President Sales & Marketing from 1996 to 1998. Mr. Savage is Chairman of the Board of EpiCept Corp., a privately held specialty pharmaceutical company focused on the development and commercialization of topically-delivered prescription pain management therapeutics. Mr. Savage also serves as a director for Noven Pharmaceuticals, a publicly-traded company which is involved in the development of advanced drug delivery technologies, and The Medicines Company, a publicly-traded specialty pharmaceutical company. He is a member of the Audit Committee and Corporate Governance and Nominating Committee.

GARY SHANGOLD, M.D., President, Chief Executive Officer and Director. Dr. Shangold joined NovaDel in December 2002 and was elected as a Director in March 2003. From May 2001 to December 2002, he had been Vice President and Regulatory Head of Drug Development at Johnson & Johnson Pharmaceutical Research and Development, LLC. From March 1999 to April 2001, Dr. Shangold was Vice President, Regulatory Franchise, Reproductive Medicine/Endocrinology/Diabetes/Wound Healing/Proof of Principle at the R.W. Johnson Pharmaceutical Research Institute. Dr. Shangold also serves on the board of Pepgen Corporation, a privately-held biopharmaceutical company. On September 2, 2005, the Company notified Dr. Shangold that his employment agreement will not be extended at the end of its term. Accordingly, the effect of this action is that Dr. Shangold s employment agreement will expire on its stated expiration date. On December 22, 2005, Dr. Shangold will therefore cease to be the President and Chief Executive Officer of the Company. The Company expects that Dr. Shangold will continue to serve as a Director until the Company s next annual stockholders meeting.

BARRY COHEN, M.B.A., Vice President of Business and New Product Development. Mr. Cohen joined NovaDel in May 2003. From September 2001 to May 2003, he was Vice President-Business Development at Keryx Biopharmaceuticals Inc. From April 2000 to September 2001, Mr. Cohen served as Vice President-Marketing at Novartis Consumer Healthcare. From 1994 to April 2000, Mr. Cohen held several executive marketing and business development positions at Novartis Consumer Healthcare.

JAN H. EGBERTS, M.D., Chief Operating Officer. Dr. Egberts joined NovaDel in September 2005. From August 2004 to September 2005, Dr. Egberts was Chief Operating Officer at Dynogen Pharmaceuticals, Inc. From February 2001 to January 2004, Dr. Egberts was Chairman of Molnlycke Healthcare, Inc., and concurrently served as President of the Barrier division from February 2001 through April 2002 and from April 2002 to January 2004 as Senior Vice President and Global Marketing Director of Molnlycke Healthcare Inc. From November 1996 to February 2001, Dr. Egberts served as Vice President, Business and Market Development Worldwide for Johnson & Johnson. Dr. Egberts is a director of Nanobac Pharmaceuticals Inc., a publicly-traded company involved in the research and treatment of degenerative diseases stemming from nanobacterial infections.

JEAN W. FRYDMAN, J.D., Vice President, General Counsel and Corporate Secretary. Ms. Frydman joined NovaDel in May 2004. From 1999 through April 2004, Ms. Frydman served as Associate General Counsel for Pharmacia Corporation and Pfizer Inc., following the acquisition of Pharmacia Corporation. Ms. Frydman is currently an Adjunct Professor at Seton Hall Law School.

HENRY KWAN, Ph.D., Head of Pharmaceutical Sciences. Dr. Kwan joined NovaDel as Head of Pharmaceutical Sciences in December 2004. From 2003 to 2004, Dr. Kwan served as Vice President, R&D and Regulatory Affairs for Eurand, Inc. In 2002, Dr. Kwan was the principal at Kwan Consulting LLC, servicing the pharmaceutical and biotechnology industries. In 2001, Dr. Kwan served as Assistant Vice President, Technical Services for Wyeth-Ayerst and from 1997 to 2000 as Vice President, Reformulation and Pharmaceutical Technology (North America) in Global Manufacturing for Warner-Lambert. Dr. Kwan ceased to be employed by the Company on October 20, 2005.

MICHAEL E. B. SPICER, Chief Financial Officer. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, 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.

AUDIT COMMITTEE

The Board of Directors has created an Audit Committee, which consists of Thomas E. Bonney, CPA (Chairman), Robert G. Savage and Dr. William F. Hamilton. Among its responsibilities, the Audit Committee selects the independent registered public accounting firm, reviews the results and scope of the audit and other services provided by the Company s independent registered public accounting firm, and reviews and evaluates the Company s internal control functions.

Our Board of Directors has determined that Mr. Bonney qualifies as an audit committee financial expert and independent director as those terms are defined by SEC regulations and the listing standards of the American Stock Exchange.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Directors, Executive Officers and beneficial owners of more than 10% of our Common Stock are required by Section 16(a) of the Exchange Act and related regulations to file ownership reports on Forms 3, 4 and 5 with the Securities and Exchange Commission and the principal exchange upon which such securities are traded or quoted and to furnish us with copies of the reports. Based solely on a review of the copies of such forms furnished to us, we believe that from August 1, 2004, to July 31, 2005, Dr. Shangold, Dr. Nemeroff, Mr. Cohen and Dr. El-Shafy were not in compliance with their respective Section 16(a) filing requirements. Dr. Shangold and Mr. Cohen each had a Form 5 reporting two transactions that were filed late; Dr. El-Shafy had one Form 5 reporting three transactions that were filed late, and Dr. Nemeroff had one Form 4 reporting one transaction that was filed late. In addition, with respect to the beneficial owners, the Company is aware that Dr. Lindsay A. Rosenwald had one Form 4 reporting one transaction that was filed late and may have failed to file two transactions on a Form 4. The Company has revised its administrative procedures to enhance the ability of the Company s Executive Officers and Directors to comply with such requirements. All others required to file reports have done so.

CODE OF ETHICS

Our Board of Directors adopted a Business Conduct Policy that is applicable to all employees of the Company. The Business Conduct Policy is intended to be designed to deter wrong-doing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, and compliance with applicable laws. The Board adopted the Business Conduct Policy before the end of calendar year 2003 and a subsequent revised Business Conduct Policy was adopted by the Board in 2004. A copy of the Business Conduct Policy can be obtained and will be provided to any person without charge upon written request to our Corporate Secretary at our executive offices, 25 Minneakoning Road, Flemington, New Jersey 08822.

The Business Conduct Policy can also be obtained on NovaDel s website, 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-KSB.

ITEM 10. EXECUTIVE COMPENSATION.

The following table sets forth a summary for the fiscal years ended July 31, 2005, 2004 and 2003, respectively, of the cash and non-cash compensation awarded, paid or accrued by the Company to our Chief Executive Officer and our five most highly compensated officers other than the CEO who served in such capacities in 2005 (collectively, the Named Executive Officers). There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2005, 2004 and 2003 to the Named Executive Officers, except as set forth below:

SUMMARY COMPENSATION TABLE

		Annual Compensation			Long-Term Compensation Awards		Payouts	
Name and Principal Position*	**Fiscal Year**	**Salary ($)**	**Bonus ($)**	**Other Annual Compensation ($)(2)**	**Restricted Stock Award(s) ($)**	**Securities Under-lying Options (1) (#)**	**LTIP Payouts ($)**	**All Other Compensation ($) (3)**
Gary A. Shangold, M.D. *President and CEO*	2005	350,000	150,000	14,795		100,000		12,596
	2004	350,000	150,000	13,393		125,000		12,057
	2003	350,000	249,780	5,871		1,000,000		
Barry C. Cohen	2005	219,387	50,000	29,552		50,000		8,447
Vice President New Business & Product Development								
	2004	193,754		27,278		75,000		7,715
	2003	34,865		2,500		75,000		
Jean W. Frydman, Esq.	2005	215,000	50,500	5,307		50,000		8,332
Vice President, General Counsel and Corporate Secretary								
	2004	42,308		854		100,000		4,615
	2003							
Mohammed Abd El-Shafy, Ph.D.,	2005	200,000		14,795				5,846
Vice President Formulation Development								
	2004	200,000	20,000	13,232		50,000		7,704
	2003	144,000		14,390		50,000		
Henry Kwan	2005	156,667		12,308		150,000		5,784
Head of Pharmaceutical Sciences								
	2004							
	2003							
Michael E. Spicer, *CPA Chief Financial Officer*	2005	146,875		17,275		100,000		6,308
	2004							
	2003					50,000		

(1) No Stock Appreciation Rights have been issued.

(2) Other Annual Compensation amounts represent certain automobile allowances paid by the Company as reimbursement for business usage of personal automobiles for: Mr. Cohen, $12,000; also includes relocation expenses: Mr. Spicer $7,121 and Dr. Kwan $5,716; and also includes employer contributions for medical, dental and life insurance benefits as follows: Dr. Shangold, $14,795; Mr. Cohen, $17,552; Ms. Frydman, $5,370; Dr. El-Shafy, $14,795; Dr. Kwan, $6,592; and Mr. Spicer, $10,154.

(3) All Other Compensation amounts represent employer contributions to 401(k) savings plan as follows: Dr. Shangold, $12,596; Mr. Cohen, $8,447; Ms. Frydman, $8,332; Dr. El-Shafy, $5,846; Dr. Kwan, $5,784 and Mr. Spicer, $6,308;

*Dr. Jan H. Egberts joined NovaDel as Chief Operating Officer on September 26, 2005 and is NovaDel s most recently hired senior executive. Although Dr. Egberts is not included in the Summary Compensation Table because he was not an Executive Officer during fiscal year 2005, information about his employment agreement is included under Employment Agreements and Change In Control Arrangements.

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OPTION GRANTS IN LAST FISCAL YEAR

(INDIVIDUAL GRANTS)

The following table sets forth information with respect to the Named Executive Officers concerning grants of options during fiscal 2005:

Option Grants in Last Fiscal Year

Individual Grants				
(a) Name	(b) Number of Securities Underlying Options Granted (#)	(c) % of Total Options Granted to Employees in Fiscal Year	(d) Exercise or Base Price ($/Sh)	(e) Expiration Date
Gary A. Shangold, M.D.	100,000	11.6%	$1.47	January 23, 2015
Barry C. Cohen	50,000	5.8%	$1.47	January 23, 2015
Jean W. Frydman, Esq.	50,000	5.8%	$1.47	January 23, 2015
Mohammed Abd El-Shafy, Ph.D.				
Henry Kwan, Ph. D.	150,000	17.3%	$1.69	December 7, 2014
Michael E. Spicer	100,000	11.6%	$1.57	December 19, 2014

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR

AND FISCAL YEAR-END OPTION VALUES

The following table sets forth information with respect to the Named Executive Officers concerning the exercise of options during fiscal 2005 and the number and value of unexercised options held as of the end of fiscal 2005.

Name of Executive Officer	**Number of Shares Acquired on Exercise**	**Value Realized ($)**	**Number of Securities Underlying Unexercised Options at Fiscal Year End; (Exercisable/Unexercisable)**	**Value of Unexercised In-the-Money Options at Fiscal Year End ($); (Exercisable/ Unexercisable)**
Gary A. Shangold, M.D.	0	0	791,667/433,333	0/0
Barry C. Cohen	0	0	125,000/75,000	0/0
Jean W. Frydman, Esq.	0	0	33,333/116,667	0/0
Mohammed Abd El-Shafy, Ph.D.	0	0	150,000	0/0
Henry Kwan, Ph. D.	0	0	0/150,000	0/0
Michael E. Spicer	0	0	0/100,000	0/0

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL ARRANGEMENTS

Gary A. Shangold, M.D. In December 2002, the Company entered into a three-year employment agreement with Dr. Shangold pursuant to which he agreed to serve as the Company s President and Chief Executive Officer. The Company agreed to pay Dr. Shangold an annual base salary of $350,000 and an annual bonus of $150,000. In addition, Dr. Shangold is eligible to receive an annual discretionary bonus of up to $262,500, which shall be determined at the sole discretion of the Board of Directors. Dr. Shangold s employment agreement also entitled him to receive an investment and fee bonus of up to $375,000 based on investments in or fees earned by NovaDel during fiscal year 2003. In fiscal year 2003, the Company paid Dr. Shangold such investment and fee bonus in the amount of $249,780. Pursuant to the employment agreement, Dr. Shangold was also granted non-plan options to purchase 1,000,000 shares of Common Stock (at an exercise price of $1.93 per share) from the 1998 Plan. Of such options, 666,666 have vested and 333,334 vest on December 3, 2005. Such options have a term of five years and expire on December 2, 2007. In the event Dr. Shangold s employment is terminated by reason of death or disability, the agreement provides for the following benefits to be paid to his estate, as applicable: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death or disability and the pro rata portion of his guaranteed bonus and stock options earned by him during the year of his death or disability; and (ii) for the shorter of twelve (12) months following his death, disability or the balance of the term of the agreement, the Company will provide continued coverage to the members of his family and, in the case of termination for disability, for Dr. Shangold, under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, for Dr. Shangold, participated immediately prior to his death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the preceding sentence to have vested) as of the date of termination shall be deemed to have expired. Any stock options that have vested as of the date of his death or disability shall remain exercisable for a period of 90

days after the date of his death or disability.

In the event that Dr. Shangold s employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Dr. Shangold s base salary for a period of one year following such termination (which shall be reduced by any amounts actually earned by Dr. Shangold during the one-year period following such termination); (ii) payment of any bonus that would have otherwise been due to Dr. Shangold by the end of the calendar year in which such termination occurs; and (iii) payment of any expense reimbursement amounts owed to Dr. Shangold through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

On September 2, 2005, the Company notified Dr. Shangold that his employment agreement will not be extended at the end of its term. Accordingly, the effect of this action is that Dr. Shangold s employment agreement will expire on its stated expiration date. On December 22, 2005, Dr. Shangold will therefore cease to be the President and Chief Executive Officer of the Company. Dr. Shangold has served as President and Chief Executive Officer of NovaDel since December 2002, and has also been a member of the Board of Directors since March 2003. The Company expects that Dr. Shangold will continue to serve as a Director until the Company s next annual stockholders meeting.

Barry C. Cohen. In May 2003, the Company entered into a three-year employment agreement with Mr. Cohen, who was appointed Vice President-New Business and Product Development. Pursuant to the agreement, he receives a base salary of $185,000, plus incentive bonuses. In addition, Mr. Cohen was issued options to purchase 75,000 shares of Common Stock at $2.04 per share under the 1998 Plan. Of such options, 55,000 have vested and 20,000 vest on May 13, 2006. These options expire in May 2008. In January 2005, Mr. Cohen was given an increase of salary to approximately $219,000 per year. In the event Mr. Cohen s employment is terminated by reason of death, the agreement provides for the following benefits to be paid to his estate: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death; (ii) continue to pay to his estate his base salary for three (3) months following his death; and (iii) for the shorter of six months following his death or the balance of the term of the agreement, the Company will provide continued coverage to the members of his family under all major medical and other health, accident, life or other disability plans and programs in which such family members participated immediately prior to his death. Any stock options granted to Mr. Cohen that have not vested as of the date of his death shall vest upon the date of Mr. Cohen s death. Should Mr. Cohen s employment be terminated due to disability, the agreement provides that the Company shall pay his base salary and any accrued bonus and expense reimbursement amounts through the date of termination. In addition, the agreement provides for the following benefits: for the shorter of six (6) months following such termination or the balance of the term of the agreement, the Company shall (i) continue to pay his base salary in effect at the time of such termination, less the amount, if any, then payable under any disability benefits of the Company and (ii) provide continued coverage under all major medical and other health, accident, life or other disability plans and programs in which Mr. Cohen participated immediately prior to such termination. All outstanding stock options, except unvested stock options, shall vest upon the effective date of his termination due to disability. In the event that Mr. Cohen s employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Mr. Cohen s base salary for a period of six months following such termination (which shall be reduced by any amounts actually earned by Mr. Cohen during the six-month period following such termination); (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursement amounts owed to Mr. Cohen through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination. Lastly, for the shorter of six months following such termination and the balance of the term of Mr. Cohen s agreement, the Company shall provide Mr. Cohen continued coverage under all major medical and other health, accident, life or other disability plans or programs in which Mr. Cohen participated immediately prior to such termination.

Jean W. Frydman, Esq. In May 2004, the Company entered into a three-year employment agreement with Jean W. Frydman, Esq., pursuant to which she agreed to serve as the Company s Vice President, General Counsel and Corporate Secretary. The Company agreed to pay Ms. Frydman an annual base salary of $200,000, and certain incentive bonuses. In January 2005, Ms. Frydman was given an increase in salary to approximately $215,000 per year. In addition, Ms. Frydman was also granted non-plan options to purchase 100,000 shares of Common Stock at an exercise price of $1.98 per share (110% of the fair market value on the grant date) which vest, subject to certain conditions, over a three-year period. Such options have a term of 10 years. On July 28, 2005, these options were exchanged for options under the 1998 Plan, the terms of which are identical to those in the original grant of non-plan options. On September 2, 2005, the Company entered into an amendment to its employment agreement with Ms. Frydman. The amendment provides for a new formula that is tied to the Company s goals, for determining Ms. Frydman s bonus payment at the end of Calendar Year 2005 and provides for increased payments upon termination of Ms. Frydman s employment in certain circumstances. In the event Ms. Frydman s employment is terminated by reason of death, the agreement provides for the following benefits to be paid to her estate: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of her death; (ii) for the shorter of six months following her death or the balance of the term of the agreement will provide continued coverage to the members of her family under all major medical and other health, accident, life or other disability plans and programs in which such family members participated immediately prior to her death.

Any stock options granted to Ms. Frydman that have not vested as of the date of her death shall be deemed to have expired as of such date. Should Ms. Frydman s employment be terminated due to disability, the agreement provides that the Company shall pay her base salary and any accrued bonus and expense reimbursement amounts through the date of termination. In addition, the agreement provides for the following benefits: for the shorter of six (6) months following such termination or the balance of the term of the agreement, the Company shall (i) continue to pay her base salary in effect at the time of such termination, less the amount, if any, then payable under any disability benefits of the Company and (ii) provide continuation coverage under all major medical and other health, accident, life or other disability plans and programs in which Ms. Frydman participated immediately prior to such termination. All stock options that have not vested as of the date of termination shall be deemed to have expired as of such date. In the event that Ms. Frydman s employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Ms. Frydman s base salary for a period of one year following such termination (which shall be reduced by any amounts actually earned by Ms. Frydman during the one-year period following termination); (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursement amounts owed to Ms. Frydman through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

Henry Kwan, Ph.D. Effective December 21, 2004, the Company entered into a three-year employment agreement with Dr. Henry Kwan pursuant to which he agreed to serve as the Company s Head of Pharmaceutical Sciences. The Company agreed to pay Dr. Kwan an annual base salary of $235,000, plus incentive bonuses. In addition, Dr. Kwan was also granted non-qualified options to purchase 150,000 shares of the Company s Common Stock at an exercise price of $1.69 per share (110% of the fair market value on the grant date) under the 1998 Plan. The options vest in three annual installments, subject to certain conditions, on December 8, 2005, December 8, 2006, and December 8, 2007. Such options have a term of 10 years and expire on December 1, 2014. Dr. Kwan was terminated without cause from employment with the Company on October 20, 2005. Pursuant to Dr. Kwan s employment agreement, the Company will continue to pay to Dr. Kwan his base salary for a period of six (6) months from October 20, 2005 and any accrued and unpaid bonus and expense reimbursement amounts through the date of termination. Such amount will be reduced by any amounts otherwise actually earned during the six-month period following the termination of his employment. In addition, for a period of one year from October 20, 2005, the Company shall provide continuation coverage under all major medical and other health, accident, life or other disability plans or programs in which Dr. Kwan participated immediately prior to his termination. All stock options granted by the Company to Dr. Kwan that had not vested as of October 20, 2005 expired on October 20, 2005 pursuant to the terms of the Employment Agreement.

Michael E.B. Spicer. Effective December 20, 2004, the Company entered into a three-year employment agreement with Michael E.B. Spicer pursuant to which he agreed to serve as the Company s Chief Financial Officer. The Company agreed to pay Mr. Spicer an annual base salary of $235,000, plus incentive bonuses. In addition, Mr. Spicer was also granted non-qualified options to purchase 100,000 shares of the Company s Common Stock at an exercise price of $1.57 per share (110% of the fair market value on the grant date) from the 1998 Plan. The options vest in three annual installments, subject to certain conditions, on December 20, 2005, December 20, 2006, and December 20, 2007. Such options have a term of 10 years and expire on December 19, 2014. On September 2, 2005, the Company entered into an amendment to its employment agreement with Mr. Spicer. The amendment provides that Mr. Spicer will receive additional amounts of money paid for relocation expenses and for expenses for temporary housing and commuting to and from his residence prior to his relocation. In the event Mr. Spicer s employment is terminated by reason of death, the agreement provides for the following benefits to be paid to his estate: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death; (ii) for the shorter of six months following his death or the balance of the term of the agreement, the Company will provide continued coverage to the members of his family under all major medical and other health, accident, life or other disability plans and programs in which such family members participated immediately prior to his death. Any stock options granted to Mr. Spicer that have not vested as of the date of his death shall be deemed to have expired as of such date. Should Mr. Spicer s employment be terminated due to disability, the agreement provides that the Company shall pay his base salary and any accrued bonus and expense reimbursement amounts through the date of termination. In addition, the agreement provides for the following benefits: for the shorter of six (6) months following such termination or the balance of the term of the agreement, the Company shall (i) continue to pay his base salary in effect at the time of such termination, less the amount, if any, then payable under any disability benefits of the Company and (ii) provide continued coverage under all major medical and other health, accident, life or other disability plans and programs in which Mr. Spicer participated immediately prior to such termination. All stock options that have not vested as of the date of termination shall be deemed to have expired as of such date.

In the event that Mr. Spicer s employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Mr. Spicer s base salary for a period of one year following such termination (which shall be reduced by any amounts actually earned by Mr. Spicer during the one-year period following such termination); (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursement amounts owed to Mr. Spicer through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

Jan H. Egberts, M.D. On September 26, 2005, the Company entered into a two-year employment agreement with Dr. Jan H. Egberts pursuant to which he agreed to serve as the Company s Chief Operating Officer. Pursuant to the agreement, Dr. Egberts will assume the position of President and Chief Executive Office on December 23, 2005. Pursuant to the agreement, Dr. Egberts receives a base salary of $350,000 and an annual bonus of 50% of his base salary as target. On the date he assumes the position of President and Chief Executive Officer, he will receive an interim bonus for the period from September 26, 2005 through the date he assumes the position of President and Chief Executive Officer, in an amount equal to 50% of his pro-rated base salary for such period. In addition, Dr. Egberts was also granted non-plan options to purchase 1,622,700 share of Common Stock (at an exercise price of $1.70 per share). The options vest in three annual installments, subject to certain conditions, on September 25, 2006, September 25, 2007 and September 25, 2008. Such options have a five-year term and expire on September 24, 2010. In addition, the Company has also agreed to grant Dr. Egberts options to purchase an additional 400,000 shares of Common Stock of the Company upon the signing of a third-party agreement which provides milestone opportunities in excess of $30 million in revenue, but no earlier than March 26, 2006. Such stock option grant will have a term of five (5) years and will vest ratably over a three-year period ending on the third anniversary of the grant. In the event Dr. Egberts s employment is terminated by reason of death or disability, the agreement provides for the following benefits to be paid to his estate, as applicable: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death or disability and the pro rata portion of his guaranteed bonus and stock options earned by him during the year of his death or disability; and (ii) for the longer of twelve (12) months following his death, disability or the balance of the term of the agreement the Company will provide continued coverage to the members of his family and, in the case of termination for disability, for Dr. Egberts, under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, for Dr. Egberts, participated immediately prior to his death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the preceding sentence to have vested) as of the date of termination shall be deemed to have expired. Any stock options that have vested as of the date of his death or disability shall remain exercisable for a period of 90 days after the date of his death or disability. In the event that Dr. Egberts employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Dr. Egberts base salary for a period of one year following such termination; (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursements owed to Dr. Egberts through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

The foregoing agreements also provide for certain non-competition and non-disclosure covenants on the part of such executive. However, with respect to the non-competition covenants, a court may determine not to enforce such provisions or only partially enforce such provisions. Additionally, each of the foregoing agreements provides for certain fringe benefits, such as inclusion in pension, profit sharing, stock option, savings, hospitalization and other benefit plans at such times as the Company may adopt them.

STOCK OPTION PLANS

The Company has three stock option plans which were adopted in 1992 (the 1992 Plan), 1997 (the 1997 Plan) and 1998 (the 1998 Plan), respectively (collectively referred to as the Plans). All three Plans have been approved by the Company s stockholders. The 1992 Plan and 1997 Plan each provide for the issuance of options to purchase 500,000 shares of Common Stock, and the 1998 Plan provides for the issuance of options to purchase 3,400,000 shares of Common Stock, for a total of 4,400,000 shares. The Plans are administered by the Compensation Committee of the Board of Directors. The Committee has sole discretion and authority, consistent with the provisions of the Plans, to select the eligible participants to whom options will be granted under the Plans, the number of shares which will be covered by each option and the form and terms of the agreement to be used. All of the Company s employees and officers are eligible to participate in the Plans.

At July 31, 2005, options to purchase 0, 0 and 860,500 shares of Common Stock were reserved for issuance pursuant to the 1992 Plan, the 1997 Plan and the 1998 Plan, respectively. The exercise prices for the outstanding options reserved under the 1992 Plan and the 1997 Plan range between $.63 and $1.67 per share; and the exercise prices for the outstanding options reserved under the 1998 Plan range between $.63 and $2.69 per share.

The Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of incentive stock options (ISOs) issued under the 1998 Plan must be equal to or greater than the fair market value of a share of common stock on the date the option is granted (110% with respect to optionees who own at least 10% of the Company s outstanding common stock). The Committee has the authority to determine the time or times at which options granted under the Plans become exercisable, but options expire no later than 5 and 10 years from the date of grant. Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only by an employee while employed by the Company or within 90 days after termination of employment (one year from termination resulting from death or disability).

No ISO may be granted to an employee if, as the result of such grant, the aggregate fair market value (determined at the time each option was granted) of the shares with respect to which ISOs are exercisable for the first time by such employee during any calendar year (under all such Plans) exceeds $100,000. The Plans do not confer upon any employee any right with respect to the continuation of employment by the Company, nor do the Plans interfere in any way with the employee s right or the Company s right to terminate the employee s employment at any time.

NON-PLAN OPTIONS

As of July 31, 2005, the Company had 4,050,000 non-plan options outstanding exercisable as follows:

$1.84 per share	$.75 per share	$1.93 per share	$1.30 per share	$1.51 per share	$3.18 per share	$3.02 per share	$1.95 per share	$1.85 per share	$1.65 per share	$2.15 per share
600,000	1,050,000	1,000,000	200,000	200,000	250,000	150,000	300,000	100,000	100,000	100,000

Following informal discussions with the staff of the American Stock Exchange (the AMEX), on July 29, 2005, the Company notified the AMEX that, since its listing on the AMEX on May 11, 2004, the Company had made seven grants of options to purchase a total of 450,000 shares of common stock of the Company (the Old Options) to six directors and one executive officer of the Company (each, a Holder) that were not issued pursuant to a plan which had previously received shareholder approval. Since Section 711 of the AMEX Company Guide provides that shareholder approval is required with respect to the establishment of a stock option plan or other equity compensation arrangement pursuant to which options may be issued to directors and officers, the grants of the Old Options appear to have violated Section 711 of the AMEX Company Guide.

The Company has in place its 1998 Stock Option Plan (the 1998 Plan), which was adopted by the Board and approved by the stockholders of the Company. Following discussions with staff members at the AMEX, on July 28, 2005, the Compensation Committee (the Committee) of the Board of Directors of the Company authorized the issuance of 450,000 new options pursuant to the 1998 Plan (the New Options) to be exchanged for the Old Options held by each of the Holders in the same amounts as the Old Options held by each Holder. The New Options contain provisions that are substantially similar to those of the Old Options. The terms and exercise prices of the New Options are identical to those of the Old Options held by each of the respective Holders. There were sufficient shares available for issuance under the 1998 Plan and the New Options could be issued under the 1998 Plan without any amendment thereof. On July 28, 2005, each of the seven Holders agreed to the exchange of the Old Options held by him or her for New Options in a like amount, and the New Options were issued to each of the Holders in amounts equal to the number of Old Options held by such Holder.

Following the Company s notification to the AMEX of the Company s noncompliance with Section 711 of the AMEX Company Guide as described above, the staff of the AMEX indicated verbally to the Company that it considers the Company s remedial actions to have brought the Company into compliance with Section 711 and that it considers the matter to be closed.

COMPENSATION OF DIRECTORS

Directors who are not employees or consultants receive fees of $2,000 for each meeting of the Board of Directors attended in person or $1,000 if participated in by telephone. Non-employee Directors are also compensated $3,000 per annum for serving, or $5,000 per annum for chairing, a committee of the Board of Directors. Each non-employee Director is also awarded options to purchase 100,000 shares of Common Stock upon their election to the Board of Directors, to vest in three equal annual installments beginning on the first anniversary of their appointment. In addition, non-employee Directors are to be awarded annually options to purchase 50,000 shares of Common Stock at the time of their re-election to the Board of Directors. Such annually awarded options vest over a three-year period. Non-employee Directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board of Directors or committees thereof.

On September 2, 2005, the Board elected Robert G. Savage, a current Director and a highly experienced professional in the pharmaceutical industry, as non-executive Chairman of the Board. Mr. Savage will continue to serve as a member of the Audit Committee and as Chairman of the Corporate Governance and Nominating Committee of the Board. There was no arrangement or understanding between Mr. Savage and any other persons pursuant to which Mr. Savage was elected non-executive Chairman of the Board of Directors and there are no related party transactions between Mr. Savage and the Company.

The Board expects to approve at a later date appropriate compensation for Mr. Savage for his services as non-executive Chairman of the Board. In addition, upon his appointment, Mr. Savage received a grant of options to acquire 400,000 shares of Common Stock of the Company at an exercise price of $1.52 per share. One hundred thousand of such options were exercisable upon the issuance date thereof, and one hundred thousand thereof become exercisable upon each of the first, second and third anniversaries of the issuance date thereof. Such options were issued under the Company s 1998 Stock Option Plan and expire on September 1, 2010.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED MATTERS.

Stock Ownership of Directors, Management and Certain Beneficial Owners

Stock Ownership of Certain Beneficial Owners

The following table sets forth information, as of October 1, 2005, regarding beneficial ownership of the Common Stock to the extent known to the Company by each person known to NovaDel to be the beneficial owner of 5% or more of the Common Stock. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

Title of Class	Name and Address or Number in Group	Amount and Nature of Beneficial Ownership	Percentage of Class
Common Stock	Lindsay A. Rosenwald, M.D. (1)	9,906,899 (2)	21.8
Common Stock	ProQuest Investments, III, L.P. (3)	4,945,876 (4)	11.8
Common Stock	ProQuest Investments, II, L.P. (3)	1,255,500 (5)	3.0
Common Stock	ProQuest Investment II Advisors Fund, L.P. (3)	30,214 (6)	*
Common Stock	Caisse De DePot Et Placement Du Quebec (7)	2,700,000 (8)	6.5

(1) The address for Dr. Rosenwald is: c/o Paramount BioCapital, Inc., 787 Seventh Avenue, 48th Floor, New York, NY 10019.

(2) Includes 5,055,660 shares of Common Stock and warrants to purchase 3,950,000 shares of Common Stock which expire in December 2008. Also includes Unit Purchase Options that include the right to receive 568,135 shares of Common Stock at a purchase price equal to approximately $1.16 per share; warrants to purchase 170,440 shares of Common Stock at an exercise price equal to $1.40 per share; and warrants to purchase 162,664 shares of Common Stock at an exercise price equal to $1.30 per share.

(3) The address for ProQuest Investments III, L.P., ProQuest Investments II, L.P., and ProQuest Investments II Advisors Fund, LP is 90 Nassau Street, 5th Floor, Princeton, NJ 08542.

(4) Includes 3,663,612 shares of Common Stock and warrants to purchase 1,282,264 shares of Common Stock at an exercise price of $1.30 per share.

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(5) Includes 930,000 shares of Common Stock and warrants to purchase 325,500 shares of Common Stock at an exercise price of $1.30 per share.

(6) Includes 22,381 shares of Common Stock and warrants to purchase 7,833 shares of Common Stock at an exercise price of $1.30 per share.

(7) The address for Caisse De DePot Et Placement Du Quebec is: 1000 Place Jean-Paul-Riopelle, Montreal, Quebec, Canada H22 263.

(8) Includes 2,000,000 shares of Common Stock and warrants to purchase 700,000 shares of Common Stock at an exercise price of $1.30 per share.

Stock Ownership of Directors and Management

The following table sets forth information, as of October 1, 2005, regarding beneficial ownership of the Common Stock to the extent known to the Company, by (i) each person who is a nominee for Director; (ii) each Executive Officer named in the Summary Compensation Table see Item 10, Executive Compensation; and (iii) all Directors and Executive Officers as a group. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

Title of Class	**Name and Address or Number in Group**	**Amount and Nature of Beneficial Ownership(2)**	**Percentage of Class**
Common Stock	Thomas E. Bonney (1)	0	*
Common Stock	Barry C. Cohen (1)	135,000	*
Common Stock	Mohammed Abd El-Shafy, Ph.D. (1)	150,000	*
Common Stock	Jean W. Frydman, Esq. (1)	33,333	*
Common Stock	William F. Hamilton, Ph.D. (1)	83,332	*
Common Stock	Lawrence J. Kessel, M.D., FACP (1)	109,597(3)	*
Common Stock	Henry Kwan, Ph.D. (1)	0	*
Common Stock	Charles Nemeroff, M.D., Ph.D. (1)	66,666	*
Common Stock	Mark H. Rachesky, M.D. (1)	1,202,379(4)	2.9
Common Stock	Robert G. Savage (1)	149,999	*
Common Stock	Gary A. Shangold, M.D. (1)	867,666	2.1
Common Stock	Michael E. B. Spicer, CPA (1)	2,500	*
	All Executive Officers and Directors as a group (13 persons)(5)	2,800,472	6.6

*less than 1%.

(1) The address of all holders listed herein is c/o NovaDel Pharma Inc., 25 Minneakoning Road, Flemington, New Jersey 08822.

(2) For each of the following persons, the numbers set forth in this column includes the number of shares of Common Stock immediately succeeding such person s name, which such person has the right to acquire within 60 days through the exercise of stock options: Mr. Cohen, 130,000; Dr. El-Shafy, 150,000; Ms. Frydman, 33,333; Dr. Hamilton, 83,332; Dr. Kessel, 89,393; Dr. Nemeroff, 66,666; Dr. Rachesky, 83,332; Mr. Savage, 149,999; Dr. Shangold, 791,666 and all Directors and Executive Officers as a group, 1,577,721.

(3) Includes 20,204 shares of Common Stock and warrants to purchase 6,061 shares of Common Stock at an exercise price equal to $1.40 per share which expire in January 2009.

(4) Includes 952,380 shares of Common Stock and warrants to purchase 166,667 shares of Common Stock at an exercise price equal to $2.00 per share which expire in April 2008. Such shares and warrants are held by MHR Capital Partnership, LP, which is controlled by Dr. Rachesky.

(5) Dr. Egberts joined NovaDel as Chief Operating Officer on September 26, 2005 and was granted non-plan options to purchase 1,622,700 shares of the Company s common stock at an exercise price of $1.70 per share. The options vest in three equal, annual installments, subject to certain conditions, on September 25, 2006, September 25, 2007, and September 25, 2008. Such options have a five-year term and expire on September 24, 2010.

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SHAREHOLDER APPROVAL OF EQUITY COMPENSATION PLANS

The following table sets forth information as of July 31, 2005 with respect to the number of shares of our common stock issuable pursuant to equity compensation plans which have and have not been approved by our stockholders.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	2,424,500	$1.58	860,500
Equity compensation plans not approved by security holders	4,050,000	$1.67	N/A
TOTAL	6,474,500	$1.64	860,500

As of July 31, 2005, we had outstanding warrants to purchase approximately 19.7 million shares of common stock, the exercise price of which ranged from $0.46 per share to $2.00 per share. Of the potential 19.7 million shares of common stock, approximately 3.1 million shares relate to warrants that were issued as compensation to various service providers. The weighted average exercise price of such warrants is approximately $1.30.

In addition, the Company granted 200,000 shares of restricted common stock to a professional service provider and its designees as a payment for services provided.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

To the best of management s knowledge, other than (i) compensation for services as Executive Officers and Directors or (ii) as set forth below, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which the Company was or was to be a party, in which the amount involved exceeds $60,000 during fiscal 2004 or fiscal 2005, and in which any Director or Executive Officer, or any security holder who is known by the Company to own of record or beneficially more than 5% of any class of the Common Stock, or any member of the immediate family of any of the foregoing persons, has an interest.

In November 2003, the Company engaged Paramount to assist it in the placement of units on a best efforts basis in connection with a private placement. In connection with such offering, the Company entered into a non-exclusive Placement Agent Agreement dated as of January 15, 2003, with Paramount, pursuant to which the Company made a cash payment equal to approximately $850,000 and issued to Paramount (and its designees) unit purchase options to purchase 1,330,303 shares of Common Stock at an exercise price equal to $1.40 per share and warrants to purchase an additional 399,091 shares of Common Stock at an exercise price of $1.40 per share. The Company also paid Paramount a non-accountable expense allowance of $25,000 to reimburse Paramount for its out-of-pocket expenses. The Company agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act. Paramount and its affiliates are beneficial owners of a significant amount of shares of common stock and securities exercisable for shares of common stock and, accordingly, Paramount BioCapital may be deemed to be an affiliate of the Company.

In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc., for the worldwide, exclusive rights to its oral spray technology to deliver propofol for pre-procedural sedation. In November 2003, the Company received $375,000 from Manhattan for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. During the years ended July 31, 2005 and 2004, the Company invoiced Manhattan approximately $119,000 and $400,000, respectively, for the Company s reimbursable expenses. Dr. Rosenwald may be deemed to be an affiliate of Manhattan.

In September 2004, the Company entered into a license and development agreement with Velcera Pharmaceuticals Inc. in connection with veterinary applications for currently marketed veterinary drugs. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the years ended July 31, 2005 and 2004, the Company invoiced Velcera approximately $183,000 and $0, respectively, for reimbursable expenses. Additionally, during the year ended July 31, 2005, the Company invoiced Velcera $50,000 for a contractual milestone that was reached. Dr. Rosenwald may be deemed to be an affiliate of Velcera.

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In October 2004, the Company entered into a license agreement with Hana Biosciences Inc., for the marketing rights in the United States and Canada for the Company s ondansetron oral spray technology. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana purchased 400,000 shares of the Company s common stock at a per share price equal to $2.50, a premium of $.91 per share or $364,000 over the then market value of the Company s common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana issued to the Company $500,000 worth of common stock of Hana (73,121 shares based on a market value of $6.84 per share). The proceeds received from Hana attributable to the premium are included in deferred revenue and are being recognized over the period of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the year ended July 31, 2005, the Company invoiced Hana approximately $84,000 for pass-through expenses incurred by the Company on behalf of Hana. Dr. Rosenwald may be deemed to be an affiliate of Hana.

During the fiscal years ended July 31, 2005 and 2004, the Company paid Robert F. Schaul, a former director and counsel of the Company, approximately $1,000 and $195,000, respectively, for legal services rendered.

During fiscal years ended July 31, 2005 and 2004, the Company paid John H. Klein, the Company s former Chairman of the Board of Directors, approximately $1,000 and $186,000, respectively, pursuant to a consulting agreement between Mr. Klein and the Company, as well as additional finder fees relating to the Company s licensing agreements. In the future, the Company may be required to pay additional fees to Mr. Klein. Such amounts, if any, will be determined by the net revenue received by the Company in connection with a license and supply agreement the Company entered into with Par Pharmaceutical, Inc.; and are primarily dependent on the amount of milestone payments received by the Company from Par Pharmaceutical. At no time will the fees be more than four percent (4%) of the net revenue received by the Company in connection with the Par Pharmaceutical agreement.

In April 2005, the Company engaged Paramount to assist it in the placement of shares in connection with a private placement. In connection with the offering, the Company paid a cash commission equal to approximately $495,000 and issued a warrant to purchase 336,651 shares of common stock to Paramount, who acted as its placement agent. Such warrant is exercisable at an initial exercise price equal to $1.30 per share (subject to adjustment). Paramount was also entitled to an expense allowance of up to $50,000 to reimburse it for its out of pocket expenses incurred in connection with the offering. The Company agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering. Paramount and its affiliates are beneficial owners of approximately 9.9 million shares of common stock and securities exercisable for shares of common stock and, accordingly, Paramount may be deemed to be an affiliate of the Company. In connection with any future offering by the Company of its debt or equity securities for gross proceeds of greater than $1 million that is intended to be exempt from Section 5 of the Securities Act on or before May 27, 2006, the Company has granted Paramount Biocapital, Inc. (Paramount) the right of first refusal to act as a placement agent or co-agent. Prior to engaging in any such offering, the Company must offer Paramount the opportunity to match the terms, conditions and limitations of any such proposed future private offering (including, but not limited to, cash fees and placement warrant coverage, if any; offering price of securities, including warrants, if any, as well as any applicable warrant exercise price and percentage of warrant coverage ; and the quality and suitability of any proposed investors as shareholders of the Company). Should Paramount be unwilling to match or propose superior terms, conditions and limitations than those offered by an alternate placement agent, the Company may engage the alternate placement agent as its exclusive placement agent, investment banker, finder or broker-dealer, as applicable, and Paramount will have no right to participate in the subsequent private offering. Should Paramount match or propose superior terms, conditions and limitations than those originally proposed by the alternate placement agent, after providing the alternate placement agent with the opportunity to match Paramount s offer, then either (i) Paramount and the alternate placement agent will each be allowed to participate in equal amounts toward the final total capital raise, as co-agents, or (ii) Paramount will be engaged by the Company to act as the exclusive placement agent for the subsequent private offering. The Board of Directors of the Company, at its sole discretion, will make the final and binding determination as to whether proposals are equal, substantially similar or superior to each other.

ITEM 13. EXHIBITS.

Exhibits are listed on the Index to Exhibits, pages E-1 through E-4, at the end of this Annual Report. The exhibits required by Item 601 of Regulation S-B, listed on such Index in response to this Item, are incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table sets forth fees billed to the Company by its independent registered public accounting firm during the fiscal years ended July 31, 2005, and 2004 for: (i) services rendered for the audit of its annual financial statements and the review of its quarterly financial statements; (ii) services by its independent registered public accounting firm that are reasonably related to the performance of the audit or review of its financial statements and that are not reported as Audit Fees; (iii) services rendered in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered.

	J.H. Cohn LLP	
	FY 2005	FY 2004
Audit Fees	$98,000	$105,000
Audit Related Fees	—	—
Tax Fees	$9,000	—
All Other Fees	—	

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

The Audit Committee currently pre-approves certain permissible non-audit services up to certain dollar limitations. The Company s management did not engage its independent registered public accounting firm to perform any such services based upon Audit Committee pre-approval. These services may include audit-related services, tax services and other services.

SIGNATURES

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

NovaDel Pharma Inc.

Date: October 27, 2005 By: /S/ GARY A. SHANGOLD
Gary A. Shangold, M.D.
President and Chief Executive Officer

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

SIGNATURES	TITLE	DATE
/S/ GARY A. SHANGOLD Gary A. Shangold, M.D.	President and Chief Executive Officer (Principal Executive Officer)	October 27, 2005