NOVADEL PHARMA INC
Form 10KSB
November 15, 2004

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, 2004

OR

[_] 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. 000-23399

NOVADEL PHARMA INC.
(Name of small business issuer as specified in its charter)

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

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822
(Address of principal executive offices) (Zip Code)

(908) 782-3431
Issuer's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Exchange Act: None

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

COMMON STOCK, PAR VALUE $.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. [ ].

State the issuer's revenues for its most recent fiscal year: $466,000

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant at November 9, 2004 was approximately $ 46,081,507 based upon the closing sale price of $1.60 for the Registrant's Common Stock, $.001 par value, as reported by the American Stock Exchange on November 9, 2004.

As of November 9, 2004, the Registrant had 33,491,437 shares of Common Stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-KSB
FOR THE FISCAL YEAR ENDED JULY 31, 2004

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NOTE: RESTATED FINANCIAL STATEMENTS

The Registrant, its Audit Committee and its current and former independent registered public accounting firms have agreed that certain of the Company's issued and outstanding stock options should be subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expense should be recognized in the Company's previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation--an interpretation of APB Opinion No. 25" (Issue Date 3/00). Accordingly, management has restated the Company's financial statements for the first three quarters of fiscal 2004, the interim periods of fiscal 2002 and 2003, and for the fiscal years 2002 and 2003. This report contains restated financial information for all of the above fiscal periods. The reasons for, and financial impact of, the adjustments are described in Note 3 of the Notes to Financial Statements set forth herein and in Item 6 "Management's Discussion and Analysis or Plan of Operation". Previously issued financial statements for such periods should not be relied upon.

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 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., is engaged in the development of novel application drug delivery systems for presently marketed prescription, over-the-counter ("OTC") and veterinary drugs. Our patented and patent-pending delivery system is a lingual 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 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 major pharmaceutical and veterinary companies, such pharmaceutical companies providing the funding for the development of specified drug products. To date, other than 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 spray, and (iv) Hana Biosciences Inc., for the marketing rights in the United States and Canada for our ondansetron lingual spray, we have not entered into any material development arrangements with any pharmaceutical companies. 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 believe that 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 have used our consulting revenues 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 a material part of our business. In 1991, we changed our name to Flemington Pharmaceutical Corporation. Effective October 1, 2002, we changed our name to NovaDel Pharma Inc. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

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) tier-one priority products for development, namely nitroglycerin, sumatriptan, alprazolam, zolpidem, ondansetron and propofol.

CARDIOVASCULAR (NITROGLYCERIN)

We have formulated our nitroglycerin product and completed stability testing of such product. A United States patent was issued in 1999 and a European patent was issued in 2003. We filed an IND with the FDA in early 2002 and began clinical trials in July 2002, which were completed in December 2002. We filed an NDA, under the guidelines of Section 505(b)(2) of the Federal Food, Drug and Cosmetic (FFDC) Act, as amended (21 U.S.C. 301 et. Seq.), with the FDA on June 16, 2004. The FDA had some outstanding administrative issues to clarify before registering the filing, namely, the status of our User Fee Exemption. The date that the issue was brought to closure is the date that our Prescription Drug User Fee Act (PDUFA) clock began (August 4, 2004). Ultimately, it was determined that a PDUFA User Fee was not required for this submission. The expected timeframe for review has been determined as 10 months, making the PDUFA date June 4, 2005. On September 27, 2004, the FDA accepted our NDA for filing.

MIGRAINE (SUMATRIPTAN) LINGUAL SPRAY

We have formulated our sumatriptan lingual spray and performed a pilot pharmacokinetic study thereof during the second quarter of calendar year 2004. On October 13, 2004, we announced the preliminary results from such pharmacokinetic study. The study indicated that the sumatriptan lingual 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 lingual spray (dose range: 2.5 mg - 30 mg) in comparison to the 50 mg oral tablet and 6 mg subcutaneous injection. For a majority of doses, we successfully delivered sumatriptan via the lingual 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 lingual 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(R)) tablet in this study, and appear to be greater than those published for the approved 20 mg Imitrex nasal spray. Absorption of the lingual 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 lingual 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 lingual spray. Furthermore, the mean time to reach maximal serum concentrations (Tmax) at the 15 mg lingual spray dose was approximately 20 minutes shorter than that achieved with the 50 mg Imitrex(R) 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 lingual 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 lingual spray had a favorable safety profile and was well-tolerated. None of the nine subjects dropped out of the study. Based on these results, we are proceeding toward the submission of an IND with the FDA and plan to move the product forward into full development, with the expectation of eventually filing an NDA under Section 505(b)(2) of the FFDC Act. We plan to optimize the current formulation going forward with appropriate modifications, including enhancements to the taste characteristics.

ANXIOLYTIC (ALPRAZOLAM) LINGUAL SPRAY

We have formulated an alprazolam lingual spray and on September 23, 2004, we announced the initiation of a pilot pharmacokinetic feasibility study in humans. Results are expected late in the fourth quarter of calendar year 2004. The study involves the administration of test drug in a range of doses into human subjects to document the profile of blood levels achieved using our proprietary lingual spray formulation of alprazolam.

HYPNOTIC (ZOLPIDEM) LINGUAL SPRAY

We have formulated a zolpidem lingual spray and we are currently conducting stability testing of the zolpidem lingual spray. A pilot pharmacokinetic study is planned for initiation late in the fourth quarter of calendar year 2004.

ANTI-EMETIC (ONDANSETRON) LINGUAL SPRAY

We have formulated an ondansetron lingual spray and we are currently conducting stability testing of the ondansetron lingual spray. A pilot pharmacokinetic study of the ondansetron lingual spray is planned for the first quarter of calendar year 2005.

ANESTHETIC (PROPOFOL) LINGUAL SPRAY

We have formulated a propofol lingual 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, our licensee and co-developer of the propofol lingual spray, has directed us to proceed with dose optimization and other formulation modifications to support full human clinical testing, targeted to start in the United States during early

calendar year 2005. Manhattan Pharmaceuticals said it plans to file an IND with the FDA by the end of calendar year 2004 for an expanded-use version of the popular anesthetic agent. The experimental product would become the first known needle-less formulation of propofol, the world's leading intravenous anesthetic, marketed as Diprivan(R). We believe that the propofol lingual 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 lingual 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.

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

ANTIHISTAMINE (CLEMASTINE) LINGUAL SPRAY

We have revised the formulation of our clemastine lingual spray and filed an IND. We initiated a pilot nasal challenge efficacy study in the second quarter of calendar year 2000 which was completed in the fourth quarter of 2000. This study tested the relative response of subjects challenged with allergy producing substances to an OTC tablet (1.34 mg) and a lingual spray dose of 0.68 mg. The antihistamine was administered 15 minutes prior to the challenge. The results showed that the spray had the same antihistaminic effect as the tablet when compared to placebo at 45 minutes after dosing even though the dose was only half that of the tablet. Eight of the parameters measured in the study showed a clear trend that the spray was better than the tablet and the tablet was better than placebo. Even though the study was only a pilot study, we feel that the results support the concept that a clemastine lingual spray could be an OTC non-sedating antihistamine product in that there were two cases of drowsiness when the tablet was given and one with the placebo but none when the lingual spray was administered. A larger confirmatory study, as well as other pilot studies, is needed.

Our antihistamine projects have been put on hold as the perceived commercial opportunity has been greatly diminished by the entry of generic versions of loratadine and clemastine into the marketplace and the switch of loratadine and clemastine from prescription to over-the-counter status.

ANTIHISTAMINE (LORATADINE) LINGUAL SPRAY

We have developed a formulation for our loratadine lingual spray formulation which has successfully undergone stability testing. We filed an IND in the fourth quarter of calendar year 2000 and a pharmacokinetic study was completed in the second quarter of calendar year 2001. We have completed a phase II clinical trial.

ESTRADIOL AND PROGESTERONE LINGUAL SPRAYS

We have formulated a lingual spray version of estradiol and have filed two INDs with the FDA in connection therewith. We have also formulated a lingual spray version of progesterone. We have performed pharmacokinetic studies in connection with both of these therapies, the results of which have confirmed our ability to deliver each of these hormones with enhanced bioavailability and with versatility in kinetic profile than with comparative solid oral dosage forms. This project has been put on hold due to questions that recently have been raised within medical literature about the proper therapeutic level of estrogen therapy.

BUSINESS DEVELOPMENT

AGREEMENT WITH MANHATTAN PHARMACEUTICALS

In April 2003, we entered into a 10-year license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our lingual 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

In July 2004, we entered into a ten-year license and supply agreement with Par Pharmaceutical, Inc., a wholly owned subsidiary of Pharmaceutical Resources, 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, other potential milestone payments if and when the NDA is approved for marketing in the United States; and royalties on net sales of the product in the United States and Canada in double-digit percentages. We are responsible for obtaining regulatory approval for the product and for supplying the product to Par Pharmaceutical.

AMENDED 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 lingual spray technology to Velcera Pharmaceuticals, Inc. of Langhorne, PA (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, Merck and Schering-Plough. We received an equity stake of 592,500 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 will be 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 upon regulatory approval on the first NDA filing and European filing. 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. The animal health market is estimated to be valued at about $14 billion per annual

worldwide. The companion pet category is the fasted growing segment, currently valued at about $5 billion per annual worldwide. Drug development by Velcera Pharmaceuticals will focus on formulating veterinary medicines that are already being marketed.

AMENDED 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 lingual 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 lingual 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 may be due to us on sales of the lingual spray version of ondansetron. 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).

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 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 have completed pilot pharmacokinetic studies for two antihistamine lingual sprays (loratadine and clemastine), an estradiol lingual spray, a progesterone lingual spray, a nitroglycerin lingual spray, a propofol lingual spray and a sumatriptan lingual spray. In addition, a phase 2 clinical trial was completed for the nitroglycerin and clemastine lingual sprays. 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. We filed a Section 505(b)(2) NDA for our nitroglycerin lingual spray in June 2004 which was accepted for filing by the FDA in September 2004. We plan to conduct pilot pharmacokinetic studies on our remaining Tier I priority products during the second half of calendar year 2004 and first quarter of calendar year 2005. The Tier I products, other than the nitroglycerin lingual spray, are lingual spray formulations of sumatriptan for which the pharmacokinetic study is complete, alprazolam for which the pharmacokinetic study has been initiated, propofol for which the pharmacokinetic study is complete. The pharmacokinetic studies for ondansetron and zolpidem are expected to be commenced during calendar year 2005. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific lingual 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 lingual spray and/or to terminate work on a specific compound which could have a material adverse effect on our operations.

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

(LINGUAL (ORAL) SPRAY).

We have certain patents and pending patent applications for our lingual 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 mouth for rapid absorption into the bloodstream via the mucosal membranes. We believe that this delivery system offers 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 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 FFDC Act. An NDA submitted under Section 505(b)(2) of the FFDC Act, 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 these Section 505(b)(2) NDA's because, although such products are known chemical entities, we or our licensees will be making new claims as to therapeutic effects or lessened side effects, or both.

We estimate that development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five 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

We intend, generally, to license products developed with our technology to other drug companies or to market our products to pharmaceutical wholesalers, drug distributors, drugstore chains, hospitals, United States governmental agencies, health maintenance organizations and other drug companies. We anticipate that promotion of our proposed products 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. Except for our agreements with Manhattan Pharmaceuticals, Par Pharmaceutical, Velcera Pharmaceuticals and Hana Biosciences, Inc., we have not entered into any agreements or arrangements with respect to the marketing of our proposed products and we may not be able to

enter into additional agreements in the future. See Item 1 "Description of Business - Business Development". If we are unable to enter into additional agreements, we may not be able to market successfully 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. Presently, we have established 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. 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. The manufacture of our pharmaceutical products is subject to current Good Manufacturing Practices (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." Since we cannot construct such a manufacturing and warehousing facility in compliance with cGMP in time to support the potential launch of our nitroglycerin lingual spray, for which an NDA has been submitted, we will use a third party contract manufacturer to satisfy our requirements. We may not be able to enter into arrangements with third party manufacturers, or be able to do so on terms favorable to us. Failure by us to complete successfully the internalization of our manufacturing requirements or to conclude an alternative contract manufacturing arrangement could have an adverse effect our efforts to obtain regulatory approval for or to commercialize our products.

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 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 (e.g., Swiss francs and Euros), 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 lingual 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 FFDC Act, 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 FFDC Act.

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 FFDC Act this time frame may be significantly shorter. We believe that most products developed in lingual 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 lingual 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) 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 lingual spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual(R) Pumpspray, a nitroglycerin lingual spray which is in an "air" propelled dispensing system (our nitroglycerin lingual spray is in 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 their RapidMist(TM) 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. Sirus Pharmaceuticals Ltd., based in the United Kingdom, also claims to be developing drugs to be delivered sublingually via an aerosol spray. Sirus is working in the areas of pain and emesis. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

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 four 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 in September 2019.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty (the "PCT") 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. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

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With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, 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 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.

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, 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 August 2020.

On February 21, 1997, we filed an application under the PCT 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. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

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 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.

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 in February 2019.

On February 21, 1997, we filed a PCT application 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. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase. 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. A European patent 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 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. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

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 in January 2024. 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 not been received from the Canadian Patent Office. Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. We have 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 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 in May 2022.

On November 9, 1998, we filed the above-identified application with the Canadian Patent Office and on October 29, 2002, a request for examination was filed. We have not yet received an office action from the Canadian Patent Office.

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 November 1, 2004, we had 28 full-time employees, two part-time employees, four of whom serve as our executive officers, 21 of whom are laboratory or support personnel and three of whom are engaged in administrative functions. Our success is dependent, in part, upon our ability to hire and retain additional manufacturing and research and development personnel; however, we may not be able to hire or retain such necessary personnel.

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, 233 Broadway, New York, New York 10279, and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661- 2511. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. 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 bcohen@NovaDel.com or contact Barry Cohen, our Vice President of Business & Product Development at our address as set forth above or at 908-782-3431 ext. 2160

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 are located at 25 Minneakoning Road, Flemington, New Jersey. The facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease. Presently, we are only occupying a portion of the office space in the building; the remaining office, laboratory, manufacturing and warehousing space is still being fitted out. We also have approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey, which also formerly housed our executive offices. We occupy that space under a five-year lease expiring in September 2005. During fiscal 2004, we paid rent for both facilities of approximately $477,000 including real estate taxes.

ITEM 3. LEGAL PROCEEDINGS.

There are no legal proceedings to which we are a party and we are not aware of any possible pending proceedings.

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

During the fourth quarter of fiscal year 2004, 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, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES.

(A) MARKET INFORMATION. Since May 11, 2004, our common stock has been traded on the AMEX under the ticket 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.

	CLOSING SALES PRICES ($)	
	HIGH	LOW
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
FISCAL 2003		
First Quarter (August 1, 2002 through October 31, 2002)	1.90	1.13
Second Quarter (November 1, 2002 through January 31, 2003)	2.80	1.44
Third Quarter (February 1, 2003 through April 30, 2003)	2.43	1.50

Fourth Quarter (May 1, 2003 through July 31, 2003)	2.20	1.50

The closing sales price of our common stock as reported by the AMEX was $1.71 on July 31, 2004.

(B) HOLDERS. As of July 31, 2004 there were approximately 156 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.

(D) RECENT SALES OF UNREGISTERED SECURITIES. During the fourth quarter of fiscal 2004, a total of 26,677 shares of our common stock were issued in connection with the cashless exercise of 29,689 options. We relied upon the exemption from registration of Section 4(2) of the Securities Act of 1933 for each of such transactions.

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

The Management's Discussion and Analysis or Plan of Operation for the years ended July 31, 2004 and 2003 presented below reflects certain restatements to the Company's previously reported results of operations for these periods. See Note 3 of the Notes to Financial Statements for a discussion of these restatements.

GENERAL

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. The Company has had a history of recurring losses from operations, giving rise to an accumulated deficit at July 31, 2004 of approximately $24,941,000. 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 enter into license agreements with drug companies who will market and distribute the final products.

The Company currently has cash and investment balances of approximately $9,400,000, which the Company believes is sufficient to maintain operating costs until the end of the calendar year 2005. The Company continues to seek collaborative arrangements with pharmaceutical companies for joint development of delivery systems and the successful marketing of these delivery systems. In view of the Company's limited resources, its anticipated expenses (resulting in significant operating losses) and the competitive environment in which the Company operates, the Company anticipates that it may, depending upon market conditions, pursue a financing by the end of the second calendar quarter of 2005. See "Liquidity and Capital Resources" below.

Over the next fiscal year, the Company will continue to stay focused on its six tier-one priority products: nitroglycerin, sumatriptan, ondansetron, zolpidem,

alprazolam and propofol.

Nitroglycerin. The Company will continue to work with the FDA concerning its review of the nitroglycerin NDA by providing any further information or support to the FDA in order to meet the PDUFA date of June 4, 2005 for anticipated approval.

Sumatriptan. The Company plans to request a pre-IND meeting with the FDA with an anticipated goal for filing the IND during first half of calendar year 2005. Subsequent to the IND submission, the Company plans to develop the clinical protocol and administer clinical trials for the sumatriptan lingual spray product.

Zolpidem and Ondansetron. The Company plans to initiate pilot pharmacokinetic studies on both of these lingual sprays with anticipated results from those studies in first calendar quarter of 2005. Depending on the results of these studies, the Company intends to develop the appropriate clinical protocol and administer the relevant trials.

Alprazolam. The Company is awaiting results of its pilot pharmacokinetic study initiated in the third quarter calendar of 2004. Depending on the results of this study, we expect to consider taking steps to file an IND and initiate full clinical development.

Propofol. We continue to support our partner, Manhattan Pharmaceuticals, in preparation of filing an IND with the FDA. Manhattan Pharmaceuticals will oversee all clinical development for this product.

Our veterinary initiatives are being undertaken with our partner, Velcera Pharmaceuticals, to determine a designated compound for formulations. It is believed that one compound will be identified by the first calendar quarter of 2005 and formulation by NovaDel is expected to be initiated subsequently.

The Company is building laboratory space in its existing headquarters (See Item 2 - "Description of Property") to handle its research and development and formulation endeavors.

The Company plans to hire a new Head of Pharmaceutical Sciences and a Chief Financial Officer as soon as practical. There also will be a need 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 overall new employees will be required in the next 12 months.

RESULTS OF OPERATIONS

FISCAL YEAR 2004 COMPARED TO FISCAL YEAR 2003

Consulting revenues for fiscal 2004 increased approximately $451,000 to $453,000 from $2,000 for fiscal 2003. This revenue increase for fiscal 2004 was primarily attributable to an increase in consulting assignments and revenue attributable to our arrangements with Manhattan Pharmaceuticals.

Research and development expenses increased approximately $1,405,000 to $2,492,000 from $1,087,000 for fiscal 2003. Consulting, selling, general and administrative expenses decreased approximately $1,377,000 or 23% to $4,627,000 from $6,004,000 for fiscal 2003.

Total costs and expenses for fiscal 2004 increased approximately $28,000 to approximately $7,119,000 compared to fiscal 2003. This increase was attributable to increased payroll expense primarily due to the hiring and recruitment of additional employees and rent expense due to the leasing and occupying of additional space for our operations. These increases were offset by a $736,000 decrease in compensation expense related to variable accounting adjustments to certain of our stock options, as well as the decreases for the fiscal 2004 period, as compared to the fiscal 2003 period, of approximately $1,147,000 in consulting fees primarily due to non-cash charges for options issued to two consultants during the fiscal 2003 period, and lower costs of clinical studies primarily due to fewer studies during the fiscal 2004 period.

Interest income increased approximately $49,000 or 100% to $98,000 for fiscal 2004 from $49,000 for fiscal 2003 due to an increased average cash balance.

Deferred income tax benefit for fiscal 2004 was approximately $214,000 compared to approximately $84,000 for fiscal 2003. These benefits resulted from the sale of our net operating losses for New Jersey income tax purposes.

The resulting net loss for fiscal 2004 was $6,341,000 compared to a net loss of $6,956,000 for fiscal 2003.

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. At July 31, 2004, we had working capital of approximately $7,676,000 as compared to working capital of $2,799,000 at July 31, 2003, representing a net increase in working capital of approximately $4,877,000. During fiscal 2004, the Company successfully closed an offering of its common stock and warrants to purchase shares of its common stock ("Private Placement"). The Private Placement provided for the sale of approximately 13.3 million shares of common stock, par value $.001 per share (the "Common Stock") and warrants to purchase 3,999,940 shares of Common Stock. The Company received proceeds, net of offering costs, of approximately $12,785,000.

Net cash used in operating activities was approximately $6,120,000 for fiscal 2004 compared to net cash used in operating activities of approximately $4,320,000 for fiscal 2003. Net cash used in operating activities for fiscal 2004 was primarily attributable to the net loss of $6,341,000 including the impact of variable plan accounting ($736,000).

The Company believes that its current cash levels together with revenues from operations, will be sufficient to satisfy its cash requirements through the end of calendar 2005. However, beyond this point the Company will likely have to obtain additional financing and/or consummate a strategic alliance with a well-funded business partner. Although the Company is actively seeking additional financing and strategic alliances, there are a number of risks and uncertainties related to its attempt to complete a financing or strategic partnering arrangement that are outside its control. The Company may not be able to successfully obtain additional financing on terms acceptable to it, or at all.

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 and 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, ACCOUNTS RECEIVABLE AND ALLOWANCE FOR DOUBTFUL ACCOUNTS - 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 uses the intrinsic value method prescribed by APB Opinion No. 25 to measure compensation expense. 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. By the second fiscal quarter of 2005, the Company expects that it will no longer be required to use variable plan accounting for stock options because the cashless exercise provision giving rise to such accounting treatment has been rescinded for outstanding options.

CAPITAL EXPENDITURES - The Company anticipates that the lab facilities in the new corporate location will be completed by the end of the first quarter of calendar 2005. The Company estimates that the costs of the build-out and necessary equipment are approximately $1,300,000.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for the years ended July 31, 2004 and 2003 were $2,492,000 and $1,087,000, respectively. Our research and development costs are expensed as incurred. These include all internal costs, external costs related to services contracted by the Company and research services conducted for others. 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. These cost categories typically include the following expenses.

Research and Pre-Clinical Operations and Direct Expenses - Clinical Trials

Research and pre-clinical operations reflect activities associated with research prior to the initiation of any potential human clinical trials. These activities predominantly represent projects associated with the formulation development of lingual sprays which may include animal safety studies, and validation testing.

Direct Expenses - Clinical Trials

Direct expenses of clinical trials include patient enrollment costs, external

site costs, expense of clinical drug supply, and external costs such as contract research consultant fees and expenses.

The following summarizes our research and development expenses by the foregoing categories for the fiscal years ended July 31, 2004 and 2003:

	FISCAL YEAR ENDED JULY 31,	
	2004	2003
RESEARCH AND DEVELOPMENT EXPENSES:		
Research and pre-clinical operations	$2,414,000	$905,0
Direct clinical trial expenses	78,000	182,0
RESEARCH AND DEVELOPMENT EXPENSES	$2,492,000	$1,087,0

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimated. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical development or pre-clinical development. The status of each of our six (6) tier-one priority products is discussed in "General," above. Successful completion of development of our six (6) tier-one priority programs is contingent on numerous risks, uncertainties, and other factors, which are described in detail in the section entitled "Risk Factors". These factors include:

- Completion of pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval
- Receipt of necessary regulatory approvals
- Obtaining adequate supplies of surfactant raw materials on commercially reasonable terms

- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials
- Performance of third-party collaborators on whom we rely heavily for the commercialization and manufacture of drug product
- Obtaining manufacturing, sales and marketing capabilities for which

we presently have limited resources

As a result of the amount and nature of these factors, many of which are outside our control, the success, timing of completion, and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- Slow patient enrollment
- Long treatment time required to demonstrate effectiveness
- Lack of sufficient clinical supplies and material
- Adverse medical events or side effects in treated patients
- Lack of effectiveness of the product candidate being tested
- Lack of sufficient funds

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our six (6) tier-one priority products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

The Company is engaged in research and development activities which often provide services and transfer rights under complex licensing agreements. The arrangements may include payment terms that include receipt of up-front fees and milestone payments. The Company has entered into such arrangements which contain multiple elements including up-front fees, milestone payments, royalty fees and equity issuances, among others. Different methods of accounting for revenue and expense recognition may be appropriate under each of these arrangements. It is currently expected that upfront and milestone payments will be recognized over the life of the relevant agreements.

The Company presently has four major agreements with Manhattan, Par, Velcera and Hana. We are entitled to certain milestone payments and double-digit royalties, generally on either net sales or gross revenues. It is speculative as to when any such payments or royalties will be earned or paid, if at all.

OFF-BALANCE SHEET ARRANGEMENTS

The Company does not have any so-called "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 PRONOUNCEMENTS

In November 2002, the FASB issued FASB Interpretation (FIN) No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a rollforward of the entity's product warranty liabilities. The Company does not expect FIN 45 to have a material impact on its financial position, results of operations or cash flows.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value base method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements are effective for our 2003 fiscal year. The interim disclosure requirements are not effective. The Company does not expect the adoption of SFAS NO. 148 to have a material impact on its financial position, results of operations or cash flows.

In January 2003, the FASB issued FIN 46, Consolidation of Variable Interest Entities. This Interpretation clarifies the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies to variable interest entities created after January 31, 2003, and is effective as of July 31, 2003 for variable interest entities created prior to February 1, 2003. The Company does not expect the adoption of FIN 46 to have a material effect on its financial position, results of operations or cash flows.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. This statement amends SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, for implementation issues related to the definition of a derivative and other FASB projects related to financial instruments. SFAS No. 149 requires that contracts with comparable characteristics be accounts for in a similar fashion. SFAS No. 149 applies prospectively to contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The Company does not expect the adoption of SFAS No. 149 to have a material effect on its financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that financial instruments within the scope of SFS No. 150 be classified as a liability or an asset. SFAS No. 150 is effective for all financial instruments entered into after May 31, 2003 and otherwise, the beginning of the first interim period after June 15, 2003. The Company does not expect the adoption of SFAS No. 150 to have a material effect on its financial position, results of operations or cash flows.

RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this Annual Report before investing in our common stock. Investing in our common stock involves a high degree of risk. Any of the following risks could adversely affect our business, financial condition and results of operations and could result in a complete loss of your investment. The risks and uncertainties described below are not the only ones we may face.

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 biopharmaceutical company. Therefore, you must evaluate us in light of the uncertainties and complexities present in 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 use 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, 2004 of approximately $24,941,000. We incurred losses in each of our last eight fiscal years, including a net loss of approximately $6,341,000 for the fiscal year ended July 31, 2004. 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 product development), our existing capital resources should be sufficient to satisfy our contemplated cash requirements through calendar year 2005. 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.

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. In addition, certain of our stockholders who purchased shares of common stock in a private placement completed by us in April and May 2003 are entitled to, until the second anniversary of the closing of each such stockholder's purchase of our common stock, purchase additional shares of our common stock in connection with subsequent offerings by us so as to maintain their prior ownership percentages. See "Risk Factors--Additional authorized shares of common stock and preferred stock available for issuance may adversely affect the market."

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 have completed pilot pharmacokinetic studies for two antihistamine lingual sprays (loratadine and clemastine), an estradiol lingual spray, a progesterone lingual spray, a nitroglycerin lingual spray, a propofol lingual spray and a sumatriptan lingual spray. In addition, we completed phase 2 clinical trials for the clemastine and nitroglycerin lingual sprays.

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. We filed an NDA for our nitroglycerin lingual spray on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We have initiated a pharmacokinetic study of an anxiolytic lingual spray and plan to conduct pilot pharmacokinetic studies on our other Tier I priority products during late calendar year 2004 and early calendar year 2005. These products are lingual spray formulations of ondansetron and zolpidem. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific lingual 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 lingual spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

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 of NovaDel, is the Chairman of the Paramount Capital, Inc., the placement agent for the private placements we completed during calendar year 2003, and the Managing Member of BioMedical Investment Group, LLC, also a major stockholder of NovaDel. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald may be deemed to beneficially own approximately 33% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald, BioMedical Investment Group and Paramount may be deemed to be our affiliates. 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 such affiliates nor Paramount or BioMedical Investment Group 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 such affiliates, Paramount or BioMedical Investment Company in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability 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 Requirements for Product Development and Commercialization" and "- Our Strategy, In Many Cases, 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 late in calendar year 2005 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. See Item 1 "Description of Business - Product Development," "Proposed Products" and "Government Regulation."

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 late in calendar year 2005 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, Inc. 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. 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. Our strategy to rely on third party marketing arrangements could adversely affect our profit margins. See Item 1 "Description of Business - Marketing and Distribution."

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. See Item 1 "Description of Business - Manufacturing."

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 purchase order agreement in place with INyX Pharmaceuticals, located in Manchester, United Kingdom. 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 to comply with its 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. See Item 1 "Description of Business - Raw Materials and Suppliers."

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

In October 2004, the Company and its independent registered public accounting firm recognized that the Company's 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 the Company's quarterly results in fiscal years 2004, 2003 and 2002. Our independent registered public accounting firm has advised us of material weaknesses noted during their audit of our 2004 financial statements. For further information concerning our internal controls, see Item 8A - "Controls and Procedures".

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. Management is currently focused on remedying internal control deficiencies, and this focus will require management from time to time to devote its attention away from other planning, oversight, and performance functions.

We will apply substantial 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 our stock price.

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 SEC regulations and 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, and we have purchased reduced coverage at substantially higher cost than in the past. We expect these efforts to require the continued commitment of significant resources. Further, our board members, Chief Executive Officer and Interim Principal 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. See Item 1 "Description of Business - Competition."

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. 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 lingual spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual(R) Pumpspray, a nitroglycerin lingual spray which is in an "air" propelled dispensing system (our nitroglycerin lingual spray is in 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 their RapidMist(TM) 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. Sirus Pharmaceuticals Ltd., based in the United Kingdom, also claims to be developing drugs to be delivered sublingually via an aerosol spray. Sirus is working in the areas of pain and emesis. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

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. We presently maintain minimal product liability insurance coverage. Although we will seek to obtain additional 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 FFDC Act, 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 FFDC. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a new drug application 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 investigative new drug application, 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 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. 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. 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. Accordingly, although the FDA has accepted our NDA for nitroglycerin lingual spray for filing, the FDA may not complete its review in a timely manner or may reject the NDA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not 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 payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

OUR STRATEGY, IN MANY CASES, 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, in many cases, 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 lingual spray technology to deliver propofol for pre-procedural sedation; an exclusive worldwide license for our proprietary lingual 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 licensed agreement with Hana Biosciences for the marketing rights in the United States and Canada for our ondansetron lingual 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 would 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 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.

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. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or 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, especially our President and Chief Executive Officer, Gary A. Shangold, M.D., our directors and our scientific advisory board members. 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.

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 50% of our common stock. 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. 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 our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our 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 described 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(R) of the National Association of Securities Dealers, Inc. During the 12-month period ended July 31, 2004, the price of our common stock has ranged from $1.35 to $2.45. 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, 2004, the average daily trading volume in our common stock was approximately 96,390 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 through the first fiscal quarter of 2005. The impact on our earnings and losses because of such expense will vary in relation to the volatility of our stock price during such quarter. (See Note 3 of the Notes to Financial Statements.)

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(R) or in the Pink Sheets(R) (a quotation medium operated by the National Quotation Bureau, 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 meritless 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, the 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. In addition, the Commission currently intends to create additional obligations with respect to the transfer of penny stocks. Most importantly, the Commission proposes that 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 may restrict the ability of broker dealers to sell our securities and may 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 our common stock. As of July 31, 2004, there were 33,091,467 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, 2004, we had outstanding stock options and warrants to purchase approximately 21,399,541 shares of our common stock, the exercise price of which range between $.63 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 2,302,500 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 1,570,500, shares have been issued under the respective stock option plans. Another 4,618,000 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 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 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 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 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 material adverse effect on the market price of our securities.

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 DEFER 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 common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

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.

Not applicable.

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 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.

Our Chief Executive Officer and our Interim Principal Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act as of the end of the period covered by this annual report on Form 10-KSB. Based on this evaluation, our Chief Executive Officer and our Interim Principal Financial Officer concluded that as of the end of the period covered by this report, except as set forth below, our disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

In connection with its audit of our financial statements for the fiscal year ended July 31, 2004, J.H. Cohn LLP, our independent registered public accounting firm, brought to the attention of the Company that certain issued and outstanding options that permit "cashless exercise" should be subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expense needed to be recognized as compensation expense in our previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation--an interpretation of APB Opinion No. 25" (Issue Date 3/00). See Note 3 to Notes to Financial Statements commencing at Page F-1 of this report.

J.H. Cohn LLP also advised the Audit Committee and management of certain material weaknesses, including the failure to record and retain comprehensive option grants issued by the Company, inability to prepare financial statements and footnotes in accordance with generally accepted accounting principles and SEC rules, a lack of an appropriate system of policies and procedures for the internal review of financial reports, including inadequate staffing, training and expertise and improper accounting procedures for grants with "cashless exercise" provisions per Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation - an interpretation of APB Opinion No. 25". J.H. Cohn LLP indicated that they considered these deficiencies to be material weaknesses as that term is defined under standards established by the Public Company Accounting Oversight Board (United States). These material weaknesses also included the following: a lack of effective documentation for stock options and other compensatory equity grants; the absence of a procedure to obtain from officers and directors information required to be disclosed about such persons; the absence or ineffectiveness of a rule compliance checking procedure for SEC filings; and lack of effective record keeping and compliance assistance for reports required

under Section 16(a) of the Exchange Act.

In light of the need for a restatement and the material weaknesses in our internal controls, commencing in the first quarter of our 2005 fiscal year, we are beginning to undertake a review of our disclosure, financial information and internal controls and procedures. This review will include efforts by our management and directors, as well as the use of additional outside resources. We are committed to addressing our control environment and reporting procedures.

Our management, including our Chief Executive Officer and Interim Principal 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 limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

(b) Changes in internal controls

Subsequent to the date of the evaluation referenced above, the Company recognized certain material weaknesses in its internal controls and procedures:

- Failure to record and retain comprehensive option grants that have been issued by the Company.
- Inability to prepare financial statements and footnotes in accordance with generally accepted accounting principles and SEC rules.
- Lack of an appropriate system of policies and procedures for the internal review of financial reports, including inadequate staffing, training and expertise.
- Improper accounting procedures for grants with "cashless exercise" provisions per Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation - an interpretation of APB Opinion No. 25".

We have rescinded our cashless exercise provision for all outstanding option grants pursuant to a resolution adopted by the Board of Directors of the Company on October 20, 2004. Thus, we expect that variable accounting will no longer be required after the end of the Company's fiscal quarter ended October 31, 2004. Nonetheless, to address weakness in recordkeeping related to issued option grants, the Company is planning to evaluate, test and install software to assist in the reconciliation of options and warrants issued by the Company.

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 our company have been 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.

ITEM 8B. OTHER INFORMATION.

Not applicable.

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. Officers are elected annually by the Board of Directors and serve at the Board of Directors' pleasure.

NAME	AGE	POSITION WITH THE COMPANY
Gary A. Shangold, M.D.	51	President, Chief Executive Officer and Director
Harry A. Dugger, III, Ph.D.	68	Chief Scientific Officer
Robert F. Schaul, Esq.	65	Secretary and Director
Donald J. Deitman	62	Chief Financial Officer
Mohammed Abd El Shafy	49	Vice President, Pharmaceutical Development
William F. Hamilton, Ph.D.	65	Director
Lawrence J. Kessel, M.D., FACP	51	Director
Mark H. Rachesky, M.D.	45	Director
Charles Nemeroff, M.D., Ph.D.	55	Director
Robert G. Savage	51	Director
Barry Cohen	41	Vice President - New Business and Product Development
Jean W. Frydman	51	Vice President-General Counsel

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. Previously he had been Vice President and Regulatory Head of Drug Development at Johnson & Johnson Pharmaceutical Research and Development, LLC. Before joining the Johnson & Johnson family of companies in 1992, he had been Medical Director of Obstetrics, Gynecology & Infertility at Serono Laboratories, Inc. and had been a member of the faculty of Obstetrics and Gynecology at the University of Chicago's Pritzker School of Medicine from 1983 to 1991. Dr. Shangold also was an Associate Clinical Professor at the Harvard University School of Medicine and a Clinical Associate at Massachusetts General Hospital. Dr. Shangold is a graduate of the University of Pennsylvania and received his M.D. from Columbia University's College of Physicians and Surgeons.

HARRY A. DUGGER, III, PH.D., Chief Scientific Officer. Dr. Dugger is the founder of NovaDel and served as its President and a Director from its inception in May 1982 until December 2002. Prior to founding NovaDel, from June 1980 to November 1982, Dr. Dugger was employed as Vice President of Research and Development by Bauers-Kray Associates, a company engaged in the development of pharmaceutical products. From 1964 to 1980, Dr. Dugger was Associate Section Head for Research and Development at Sandoz Pharmaceuticals Corporation. Dr. Dugger received an M.S. in Chemistry from the University of Michigan in 1960 and received a Ph.D. in Chemistry from the University of Michigan in 1962.

DONALD DEITMAN, Former Chief Financial Officer. Mr. Deitman joined NovaDel in 1998. From 1988 until joining NovaDel, Mr. Deitman was employed as a business consultant implementing multi-module MRP II software systems. From 1982 to 1988, Mr. Deitman was corporate controller for FCS Industries, Inc., of Flemington, New Jersey. Mr. Deitman received a B.S. in Accounting from Rutgers University in 1972. Mr. Deitman retired from the Company in September 2004.

ROBERT F. SCHAUL, ESQ., Former Secretary and Director. Mr. Schaul had been a Director of NovaDel since November 1991 and Vice President, Secretary and General Counsel of NovaDel from November 1991 to February 1995. He advised NovaDel since its formation. Mr. Schaul is also a part-time Municipal Court Judge for a number of New Jersey municipalities. From 1995 to 1998, Mr. Schaul was Vice President and General Counsel of Landmark Financial Corp. Mr. Schaul received a B.A. from New York University in 1961 and a J.D. from Harvard University in 1964. Mr. Schaul left the Company in July 2004.

WILLIAM F. HAMILTON, PH.D., Director. Dr. Hamilton was elected to our Board 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 company developing a drug manufacturing process and proprietary drugs. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of the Board's Audit Committee of which he is our Chairman, as well as our Corporate Governance and Nominating Committee and Compensation Committee.

LAWRENCE JAY KESSEL, M.D., FACP, Director. Dr. Kessel was elected to our Board in March 2003. Dr. Kessel, a physician, is President of Lawrence J. Kessel, M.D., & Associates, PC, a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He received a B.S. degree from the University of Pittsburgh with honors in Biology and subsequently graduated with an M.D. degree from Temple Medical School. He completed a formal residency in Internal Medicine at Abington Memorial Hospital, and is Board Certified in

Internal Medicine with added qualification as a diplomat in Geriatric Medicine. 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. and BioPharma, Inc. He previously served on the Board of Directors of Genta Incorporated. He is a member of our Compensation Committee and Corporate Governance and Nominating Committee.

MOHAMMED ABD EL SHAFY, PH.D., Vice President-Pharmaceutical Development. Dr. El-Shafy joined NovaDel in May 2002. From 1999 to 2002 he was employed as a Team Leader and Senior Scientist with Nastech Pharmaceutical Inc., Hauppauge, New York. From 1998 to 1999 Dr. El-Shafy was a Post-Doctoral Fellow at the University of Wisconsin's School of Pharmacy. He received his doctorate in 1997 from the School of Pharmacy, University of Wales, Cardiff, Wales, UK. From 1983 to 1993 he was an Assistant Lecturer of Pharmaceutical Sciences on the Faculty of Pharmacy, Al-Azhar University, Cairo, Egypt.

BARRY COHEN, Vice President of New Business and Product Development. Mr. Cohen joined NovaDel in May 2003. Before joining NovaDel, he was Vice President-Business Development at Keryx Biopharmaceuticals Inc., and before that held several executive marketing and business development positions at Novartis Consumer Health. Mr. Cohen holds a B.B.A. in Marketing from Hofstra University and an M.B.A in Marketing from Pace University.

JEAN W. FRYDMAN, J.D., Vice President, Secretary and General Counsel. Ms. Frydman joined NovaDel in May 2004, bringing more than 20 years experience in the pharmaceutical, medical device and biotechnology industries. She has been part of Counsel's Office for several major companies such as Abbott Laboratories, Knoll Pharmaceuticals, Pharmacia Corp. and most recently with Pfizer Inc. Ms. Frydman also practiced law with the firm of Fenwick & West, LLP in its Washington D.C. office where she specialized in regulatory law for biotechnology companies. She is currently Adjunct Professor at Seton Hall Law School.

MARK H. RACHESKY, M.D., Director. Dr. Rachesky joined our Board in June 2003. Dr. Rachesky is the founder and 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 company developing a drug manufacturing process and proprietary drugs. Dr. Rachesky is a graduate of Stanford University School of Medicine, and Stanford University School of Business. Dr. Rachesky graduated from the University of Pennsylvania with a B.S. in Molecular Aspects of Cancer.

CHARLES NEMEROFF, M.D., PH.D., Director. Dr. Nemeroff joined our Board 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. He has served on the Mental Health Advisory Council of the National Institute of Mental Health and the Biomedical Research Council for NASA. Dr. Nemeroff is a past President of the American College of Psychiatrists and a past President of the American College of Neuropsychopharmacology and is Editor-in-Chief of Neuropsychopharmacology. He has served as Editor-in-Chief of the Psychopharmacology Bulletin, Associate Editor of Biological Psychiatry and as

the Co-Editor-in-Chief of both Critical Reviews in Neurobiology and Depression and Anxiety. Dr. Nemeroff serves on the Scientific Advisory Board of numerous pharmaceutical companies, including Acadia Pharmaceuticals, Astra-Zeneca Pharmaceuticals, Forest Laboratories, Janssen, Organon, Glaxo-SmithKline Beecham and Wyeth-Ayerst. Dr. Nemeroff has received numerous awards for his research, including the Bowis Award from the American College of Psychiatrists and the Menninger Prize from the American College of Physicians. In 2002, he was elected to the Institute of Medicine. He is a member of the Compensation Committee.

ROBERT G. SAVAGE, M.B.A., Director. From March 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. From 1985 to 1996, Mr. Savage held several positions at Hoffmann-La Roche, Inc., a healthcare firm. Mr. Savage also serves as a director for Noven Pharmaceuticals, a leader in the development of advance drug delivery technologies, and Medicines Company, a specialty pharmaceutical company. Mr. Savage received a B.S. in biology from Upsala College and an M.B.A. from Rutgers University. He is a member of our Audit Committee and Corporate Governance and Nominating Committee.

CODE OF ETHICS

Our Board of Directors adopted a Code of Ethics to be applicable to all employees. The Code of Ethics 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 Code of Ethics before the end of calendar year 2003 and a subsequent revised Code of Ethics was adopted by the Board in August 2004. A copy of the Code of Ethics can be obtained and will be provided to any person without charge upon written request to our Secretary at our executive offices, 25 Minneakoning Road, Flemington, New Jersey 08822.

The Code of Business Conduct can 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.

AUDIT COMMITTEE

The Audit Committee consists of Robert Savage and Dr. William Hamilton (Chairman). The Audit Committee selects the independent registered public accounting firm, review 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.

At this time, we do not have on our Audit Committee an "audit committee financial expert" within the meaning of the Federal laws. We are presently seeking to identify an individual willing to serve on our Board who would qualify as an audit committee financial expert.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires officers, directors and other persons who own more than 10% of a class of equity securities registered pursuant to Section 12 of the Exchange Act to file reports of ownership and changes in ownership with both the SEC and the principal exchange upon which such securities are traded or quoted. Officers, directors and persons holding greater than 10% of our outstanding common stock ("Reporting Persons") are also required to furnish us with copies of any such reports filed pursuant to Section 16(a) of the Exchange Act. Based solely on a review of the copies of such forms furnished to us, we believe that from August 1, 2003, to July 31, 2004, Gary A. Shangold, Barry C. Cohen and Mohammed Abd El Shafy were not in compliance with their respective Section 16(a) filing requirements. We have revised our administrative procedures to enhance the ability of our Reporting Person comply with such requirements. All others required to file reports have done so.

ITEM 10. EXECUTIVE COMPENSATION.

EXECUTIVE COMPENSATION

The following table sets forth a summary for the fiscal years ended July 31, 2004, 2003 and 2002, respectively, of the cash and non-cash compensation awarded, paid or accrued by the Company to our Chief Executive Officer and our four most highly compensated officers other than the CEO who served in such capacities at the end of fiscal 2004 (collectively, the "Named Executive Officers"). There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2002, 2003 and 2004 to the Named Executive Officers, except as set forth below:

SUMMARY COMPENSATION TABLE

		ANNUAL COMPENSATION			LONG-TERM AWARDS	
NAME AND PRINCIPAL POSITION	FISCAL YEAR	SALARY ($)	BONUS ($)	OTHER ANNUAL COMPENSATION ($)	RESTRICTED STOCK AWARD(S) ($)	S U
Gary A. Shangold, M.D. President and CEO	2004	350,000	150,000			
	2003	350,000	249,780	0	0	1
Harry A. Dugger, III, Ph.D. Chief Scientific Officer, formerly President and CEO	2004	274,000	--	--	--	
	2003	246,900	0	0	0	
	2002	347,000	0	0	0	
Donald Deitman Chief Financial Officer	2004	138,000				

	2003	124,200	0	0	0
	2002	104,400	0	0	0
Mohammed Abd El Shafy, Ph.D., Vice President - Formulation Development	2004	200,000	20,000	0	0
	2003	144,000	0	0	0
Jean W. Frydman Vice President, Secretary & General Counsel	2004	42,308 *	0	0	0
* Partial year					
Barry C. Cohen Vice President - New Business & Product Development	2004	193,754	0	0	0

(1) No Stock Appreciation Rights have been issued.

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 2004:

OPTION/SAR GRANTS IN LAST FISCAL YEAR			
	Individual Grants		
(a)	(b)	(c)	(
Name	Number of Securities Underlying Options/SARs Granted (#)	% of Total Options/SARs Granted to Employees in Fiscal Year	Exerci Pric
Gary A. Shangold, M.D.	125,000	9.5%	
Harry A. Dugger III, Ph.D.	50,000	3.8%	
Donald J. Deitman	0	N/A	
Mohammed Abd El Shafy, Ph.D.	50,000	3.8%	
Barry C. Cohen	75,000	5.7%	
Jean W. Frydman	100,000	7.6%	

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 exercises of options during fiscal 2004 and the number and value of unexercised options held as of the end of fiscal 2004.

NAME OF EXECUTIVE OFFICER	NUMBER OF SHARES ACQUIRED ON EXERCISE	VALUE REALIZED ($)	NUMBER OF SECURITIES UNDERLYIN UNEXERCISED OPTIONS AT FISCAL Y END; (EXERCISABLE/UNEXERCISABL
Harry A. Dugger, III, Ph.D.	0	-	970,000/0
Gary A. Shangold, M.D.	0	-	458,333/667,000
Donald Deitman	0	-	-
Mohammed Abd El Shafy, Ph.D.	0	-	200,000/50,000
Barry Cohen	0	-	20,000/130,000
Jean Frydman	0		0/100,000

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL ARRANGEMENTS

GARY A. SHANGOLD, M.D. In December 2002, we entered into a three-year employment agreement with Dr. Shangold pursuant to which he agreed to serve as our President and Chief Executive Officer. We agreed to pay Dr. Shangold an annual base salary of $350,000 and a guaranteed bonus of $150,000. In addition, Dr. Shangold is eligible to receive: (i) an annual discretionary bonus of up to $262,500, which shall be determined at the sole discretion of the Board; and (ii) an investment and fee bonus equal to 5% of all amounts up to an aggregate of $7,500,000 (I.E., $375,000 in bonus) invested in, or earned by, NovaDel during the term of his agreement. We paid Dr. Shangold a contractual bonus of $200,000 during the fourth quarter of fiscal year 2003 and $49,780 in calendar year 2004. Pursuant to the agreement, Dr. Shangold was also granted Non-plan options to purchase 1,000,000 shares of our common stock (at an exercise price of $1.93 per share) which vest over a three-year period.

HARRY A. DUGGER, III, PH.D. In February 2002, effective January 1, 2002, we entered into a new three-year employment agreement with Dr. Dugger at a base salary, for the first year, of $248,500 per year (which increases each year by the greater of the CPI index or 5%). His agreement will expire January 2005, at which time it is expected that he will retire and no longer be an employee of the Company.

DONALD DEITMAN. In February 2002, effective January 1, 2002, we entered into a

three year employment agreement with Mr. Deitman pursuant to which he agreed to serve as our Chief Financial Officer. The agreement provided for a base salary, for the first year, of $125,000 per year (which increases each year by the greater of the CPI index or 5%). At the end of the fiscal year his salary was 137,812 per year. Mr. Deitman subsequently retired in September 2004.

MOHAMMED ABD EL SHAFY, PH.D. In May 2002, we entered into a three year employment agreement with Dr. El-Shafy, who was appointed Vice President-Pharmaceutical Development. Pursuant to the agreement, he received a base salary, for the first year, of $110,000, which increased in April 2003 to $180,000. In April 2004, he entered into an amended employment agreement for an additional three year term at a base salary of 200,000 per year. Since his employment, he has been granted 150,000 Non-plan options at $3.02 per share and an additional 50,000 options at $1.51 per share and another 50,000 options at $1.65 per share under the 1998 Option Plan.

BARRY COHEN. In May 2003, we entered into a three year employment agreement with Barry 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. Pursuant to the agreement, he was issued 75,000 options (exercisable at $2.04 per share) under the 1998 Plan. 60,000 of such options vest in three equal installments commencing May 2004. These options expire in May 2008. The balance of such options vest upon achievement of certain objectives. In January 2004, Mr. Cohen was given an increase of salary to $200,000 per year and an additional stock option grant of 75,000 shares at a price of $1.65 per share.

JEAN FRYDMAN. 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 and General Counsel. The Company agreed to pay Ms. Frydman an annual base salary of $200,000. Pursuant to the agreement, Ms. Frydman was also granted Non-plan options to purchase 100,000 shares of the Company's 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 conditions, over a three-year period. Such options have a term of 10 years.

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 we may adopt them.

STOCK OPTION PLANS

We have three stock option plans, adopted in 1992, 1997 and 1998, respectively (collectively referred to as the "Plans"). The 1992 and 1997 Plans 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 1997 Stock Option Plan is administered by William Hamilton, Lawrence Kessel and Charles Nemeroff who constitute the Compensation Committee of the Board of Directors ("Committee"), and the 1992 Stock Option Plan and 1998 Stock Option Plan are administered by the entire Board of Directors. For purposes of the following discussion, the term "Committee" will be used to reference the Committee with respect to the 1997 Stock Option Plan and the entire Board of Directors with respect to the 1992 Stock Option Plan and 1998 Stock Option Plan, as applicable. 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 our employees and officers are eligible to participate in the Plans.

At July 31, 2004, 0, 0 and 1,829,500 shares of our common stock were reserved for issuance pursuant to the 1992, 1997 and 1998 Plans, respectively. The exercise prices for the outstanding options reserved under the 1992 and 1997 Plans range between $.63 and $2.00 per share; and the exercise prices for the outstanding options reserved under the 1998 Plan range between $1.30 and $1.99 per share.

The Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of ISOs 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 our 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 ten years from the date of grant (five years with respect to Optionees who own at least 10% of our outstanding common stock). Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only by an employee while employed by us 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 of NovaDel and any parent and subsidiary) exceeds $100,000. The Plans do not confer upon any employee any right with respect to the continuation of employment by us, nor do the Plans interfere in any way with the employee's right or our right to terminate the employee's employment at any time.

NON-PLAN OPTIONS

As of July 31, 2004, we had 3,950,000 Non-plan options outstanding as follows: 600,000 options exercisable at $1.84 per share; 1,050,000 options exercisable at $.75 per share; 1,000,000 options exercisable at $1.93 per share; 200,000 options exercisable at $1.30 per share; 200,000 options exercisable at $1.51 per share; 250,000 options exercisable at $3.18 per share; and 150,000 options exercisable at $3.02 per share; 300,000 options exercisable at $1.95 per share; 100,000 options exercisable, at $1.85 and 100,000 options exercisable at $1.65 per share.

COMPENSATION OF DIRECTORS

Our Directors are elected annually and serve until the next annual meeting of stockholders and until a successor shall have been duly elected and qualified. Effective September 2003, our 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. Directors are also compensated $3,000 per annum for serving or $5,000 per annum for chairing a committee of the Board of Directors. Such Directors also are awarded 100,000 Non-plan Options 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, such Directors are to be awarded an additional 50,000 Non-plan Options at the time of their re-election of the Board, i.e., at the annual meeting. Such annually awarded options also vest over a three-year period. Such Directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board of Directors or committees. Directors may be removed with or without cause by a vote of the majority of the stockholders then entitled to vote.

In March 2003, we issued 100,000 Non-plan Options to each of Dr. Hamilton and Dr. Kessel upon their being elected to the Board of Directors. In March 2003, we also issued 10,000 options to each of Messrs. Schaul and a former director under the 1998 Plan. All of these options have an exercise price of $1.51; the options issued to Messrs. Schaul and a former director vested immediately, those issued to Drs. Hamilton and Kessel vest in three equal annual installments beginning in March 2004 and expire in March 2008. In April 2004, both Dr. Hamilton and Dr. Kessel were issued 50,000 options, respectively at an exercise price of $1.95. These options will vest in three equal annual installments.

In June, 2003, we issued 100,000 Non-plan Options to Dr. Rachesky upon his being appointed to the Board of Directors. These options have an exercise price of $2.15 and vest in three equal annual installments beginning in June 2004 and expire in June 2008. Dr. Rachesky was issued an additional 50,000 options at an exercise price of $1.95. These options will vest in three equal annual installments.

In September 2003, we issued 100,000 Non-plan Options to Dr. Nemeroff upon his being elected to the Board of Directors. Strike price for these options is $1.95. These options vest in three equal annual installments and expire in September 2008. Dr. Nemeroff was than granted 50,000 Non-plan Options on April 2004, at a strike price of $1.95. These options will expire in April, 2009 and vest annually over the next three years.

An additional member, Robert Savage, was appointed to the Board of Directors in early calendar 2004. Upon appointment, he received 100,000 options at an exercise price of $1.65 per share. The options vest in three equal annual installments. The option grants expire February, 2009. He received an additional 50,000 Non-plan Options on April 2004 at a strike price of $1.95. These options expire in April, 2009 and vest annually over the next three years.

There were no other arrangements pursuant to which any Director was compensated during fiscal 2004 for any services provided as a Director.

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

The following table sets forth information, as of July 31, 2004, with respect to the beneficial ownership of the outstanding shares of our common stock as of such date plus, where relevant for particular beneficial owners, shares which such beneficial owner has the right to acquire within 60 days, by (i) any holder known to us owning more than five percent (5%) of the outstanding shares; (ii) our officers and directors; and (iii) the directors and officers of NovaDel as a group:

TITLE OF CLASS	NAME AND ADDRESS OR NUMBER IN GROUP(1)	AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP
Common Stock	Harry A. Dugger, III, Ph.D.	2,154,003(2)
Common Stock	Gary A. Shangold, M.D.	458,333(3)
Common Stock	Robert Savage	0(4)
Common Stock	Donald Deitman	0
Common Stock	Jean W. Frydman, Esq.	0(5)
Common Stock	Mohammed Abd El Shafy, Ph.D.	250,000(6)
Common Stock	William F. Hamilton, Ph.D.	33,333(7)
Common Stock	Lawrence J. Kessel, M.D., FACP	33,333(7)
Common Stock	Barry Cohen	95,000(8)
Common Stock	Mark H. Rachesky, M.D.	1,119,047(9)
Common Stock	Charles Nemeroff, M.D., Ph.D.	0(10)
Common Stock	Lindsay A. Rosenwald, M.D.	13,233,334(11)
Common Stock	Biomedical Investment Group, LLC	5,333,334(12)
Common Stock	All Executive Officers and Directors as a group (11 persons)	4,109,716 (2)(3)(4) (6)(7)(8)(9)(10)

* DENOTES LESS THAN ONE PERCENT (1%).

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

(2) Includes options to purchase 200,000 shares of common stock (exercisable at $.70 per share) issued under the 1992 Stock Option Plan which expire in July 2006; options to purchase 50,000 shares of common stock (exercisable at $.70 per share) under the 1997 Stock Option Plan which expire in December 2006; options to purchase 95,000 shares of common stock (exercisable at $.70 per share) issued under the 1998 Stock Option Plan which expire in January 2005; options to purchase 300,000 shares of common stock issued outside of the Plans (exercisable at $1.84 per share) which expire November 2007; options to purchase 200,000 shares of common stock issued outside of the Plans (exercisable at $1.30 per share) which expire October 2007; options to purchase 75,000 shares of common stock (exercisable at $1.30 per share) issued under the 1998 Stock Option Plan, which expire in October 2007; options to purchase 50,000 shares of common stock (exercisable at $1.82 per share) issued under the 1998 Stock Option Plan which expire in February 22, 2009; 152,000 shares owned by his daughter Christina Dugger; and 152,000 shares owned by his son Andrew Dugger.

(3) Does not include two-thirds of Non-plan Options, issued in December 2002, to purchase 1,000,000 shares of common stock at an exercise price of $1.93 per share. These options vest in three equal annual installments, beginning in December 2003, and expire in December 2007. It includes one-third of the

1,000,000 shares and additional options to purchase 125,000 shares of common stock (exercisable at $1.82 per share issued under the 1998 Stock Option Plan, which expire in February 2009.

(4) Mr. Savage was granted Non-plan options to purchase 100,000 shares of common stock at an exercisable price of $1.65 per share, which shall vest in three annual installments beginning in February 2005. Not included were an additional grant of 50,000 shares of Non-plan Options at an exercisable price of $1.95 per share which shall vest in three annual installments beginning April 2005.

(5) Does not include 100,000 Non-plan Options exercisable at $1.98 per share. These options vest in three equal annual installments beginning in May 2005 and expire May 2014.

(6) Includes 150,000 Non-plan Options exercisable at $3.02 per share; These options expire in May 2012. Also includes 50,000 options issued under the 1998 Option Plan to purchase common stock at an exercise price of $1.51 per share, expiring in March 2008 and 50,000 options issued under the 1998 Option Plan to purchase common stock at an exercise price of $1.65 per share expiring in February 2009.

(7) Does not include options to purchase 66,667 shares of common stock at an exercise price of $1.51 per share, which shall vest in two annual installments beginning March 2005. The options expire in March 2008. Does not include options to purchase 50,000 shares of common stock at an exercise price o $1.95 which will vest in three annual installments beginning April 2005.

(8) Does not include 55,000 options issued under the 1998 Plan, to purchase common stock at an exercise price of $2.01 per share. The options expire in May 2008 and vest subject to certain conditions.

(9) Does not include options to purchase 66,667 shares of common stock at an exercise price of $2.15 per share, which shall vest in two annual installments beginning in June 2005. Does not include 50,000 Non-plan Options exercisable at $1.95 per share, which shall vest in three annual installments beginning April 2005. Includes 952,380 shares of common stock and warrants to purchase 166,667 shares of common stock at an exercise price of $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.

(10) Does not include options to purchase 100,000 shares of common stock at an exercise price of $1.85 per share, which shall vest in three annual installments beginning September 2004. Does not include 50,000 Non-plan Options exercisable price of $1.95 per share which shall vest in three annual installments beginning April 2005.

(11) Includes 3,950,000 shares of common stock and warrants to purchase 3,950,000 shares of common stock at an exercise price of $.75 per share which expire in December 2008. Also includes 2,666,667 shares of common stock and 2,666,667 warrants to purchase 2,666,667 shares of common stock, which expire in February 2009, owned by Biomedical Investment Group.

(12) Includes warrants to purchase 2,666,667 shares of common stock at an exercise price of $.75 per share which expire in February 2009.

SHAREHOLDER APPROVAL OF EQUITY COMPENSATION PLANS

The following table sets forth information as of the end of fiscal 2004 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, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Numb remai f
	(a)	(b)	
Equity compensation plans approved by security holders	0	N/A	
Equity compensation plans not approved by security holders	3,717,472	$1.658	
TOTAL	3,717,472	$1.658	

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

To the best of management's knowledge, other than (i) compensation for services as officers and directors described under Item 10 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 we were or are to be a party, in which the amount involved exceeds $60,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

During December 2001, we received net proceeds of approximately $3,000,000 from a private placement of 4,000,000 units, which were purchased by Dr. Rosenwald. Each unit consisted of one share of common stock, and a warrant (which expires December 2008) to purchase an additional share of our common stock at an exercise price of $.75. As part of the purchase agreement, we agreed to elect to the Board of Directors, a Director to be nominated by Dr. Rosenwald (as of the date hereof, no such nominee had been selected) and to permit Dr. Rosenwald or a representative of his to attend meetings of our Board of Directors. Appropriate confidentiality and non-disclosure agreements are in place to protect our confidential information.

In March 2002, we received net proceeds of approximately $2,000,000 from a private placement of 2,666,667 additional units at a sale price of $.75 per unit. These units were purchased by Biomedical Investment Group which is affiliated with Dr. Rosenwald. These warrants expire in March 2009.

In April and May 2003, we engaged Paramount Capital to assist us in the placement of units on a "best efforts" basis in connection with a private

placement. In connection with this offering, we entered into a non-exclusive Placement Agent Agreement dated as of January 15, 2003, with Paramount Capital, pursuant to which we paid to Paramount for its services, a cash payment equal to approximately $360,000 and issued to Paramount or its designees 160,017 warrants with an exercise price equal to $1.65 per share and warrants to purchase 40,004 shares of common stock at an exercise price equal to $2.00 per share. We also agreed to pay to Paramount a non-accountable expense allowance equal to $25,000 to reimburse Paramount for its out-of-pocket expenses. Lastly, we agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

In November 2003, we engaged Paramount Capital to assist us in the placement of units on a "best efforts" basis in connection with a private placement. In connection with this offering, we entered into a non-exclusive Placement Agent Agreement dated as of January 15, 2003, with Paramount Capital, pursuant to which we made a cash payment equal to approximately $850,000 and issued to Paramount Capital (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. We also paid Paramount Capital a non-accountable expense allowance of $25,000 to reimburse Paramount Capital for its out-of- pocket expenses. Lastly, we agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our lingual spray technology to deliver propofol for pre-procedural sedation. In September 2004, we entered into a license and development agreement with Velcera Pharmaceuticals Inc. a veterinary company. In October 2004, we entered into a license agreement with Hana Biosciences for the marketing rights in the United States and Canada for our ondansetron lingual spray technology. Dr. Rosenwald may be deemed to be an affiliate of Manhattan, Velcera and Hana.

During fiscal 2004, we paid Mr. Schaul, a former director, approximately $195,000, and approximately $160,000 for fiscal 2003, for legal services rendered.

During fiscal 2004, we paid Mr. Klein, our former Chairman of the Board, approximately $186,000 and approximately $300,000 for fiscal 2003, pursuant to our consulting agreement with Mr. Klein , as well as additional finder fees relating to the Company's licensing agreements. The amount of the additional fees will be determined by the net revenue received by us in connection with the Par Pharmaceutical agreement. The amount of fees paid to Mr. Klein will fluctuate over the term of the agreement, primarily dependent on the amount of milestone payments received by the Company. 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.

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 us by our independent registered

public accounting firms during the fiscal years ended July 31, 2004, and July 31, 2003, for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; (ii) services by our independent registered public accounting firms that are reasonably related to the performance of the audit or review of our 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.

	JULY 31, 2003	JULY 31, 2004
Audit Fees	$21,541	$20,000
Audit Related Fees	$ --	$11,802
Tax Fees	$ 5,000	$ 1,790
All Other Fees	$ 6,675	$ --

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: November 15, 2004

By: /S/ GARY A. SHANGOLD
Gary A. Shangold, M.D.
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
/S/ GARY A. SHANGOLD Gary A. Shangold, M.D.	President and Chief Executive Officer (Principal Executive Officer) and Director
/S/ HOWARD KANCE Howard Kance	Interim Principal Financial Officer (Principal Financial Officer)
/S/ WILLIAM F. HAMILTON William F. Hamilton, Ph.D.	Director
/S/ LAWRENCE J. KESSEL Lawrence J. Kessel, M.D., FACP	Director

/S/ MARK H. RACHESKY — Director

Mark H. Rachesky, M.D.

/S/ CHARLES NEMEROFF — Director

Charles Nemeroff, M.D., Ph.D.

/S/ROBERT G. SAVAGE — Director

Robert G. Savage

INDEX TO FINANCIAL STATEMENTS AND
RESTATEMENT OF QUARTERLY DATA

The following financial statements are included in Part II, Item 7:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and
Board of Directors of
NovaDel Pharma Inc.

We have audited the accompanying balance sheet of NovaDel Pharma Inc. as of July 31, 2004, and the related statements of operations, stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial

statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. as of July 31, 2004, and its results of operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/S/ J.H. COHN LLP

Roseland, New Jersey
November 11, 2004

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of
NovaDel Pharma Inc.

We have audited the restated financial statements of NovaDel Pharma Inc., (formerly Flemington Pharmaceutical Corporation) as of July 31, 2003 and 2002 and for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. at July 31, 2003 and 2002, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the financial statements, previously unrecognized compensation expenses were discovered in the current year affecting the fiscal 2003 and 2002 financial statements. Accordingly, the accompanying balance sheets as of July 31, 2003 and 2002 and related statements of operations, stockholders' equity and cash flows for the years then ended have been restated.

/s/ WISS & COMPANY, LLP

Livingston, New Jersey
September 8, 2003, except for Notes 2 and 3
which are as of November 11, 2004

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NOVADEL PHARMA INC.
BALANCE SHEETS
AS OF JULY 31, 2004 AND 2003

ASSETS	July 31, 2004	July 31, 2003 As Restated (Note 3)
Current Assets:		
Cash and cash equivalents	$ 2,166,000	$ 3,086,000
Short term investments	6,211,000	--
Accounts receivable - trade	130,000	2,000
Prepaid expenses and other current assets	255,000	168,000
Total Current Assets	8,762,000	3,256,000
Property and equipment, net	1,066,000	714,000
Long term investments	1,307,000	--
Other Assets	351,000	357,000
TOTAL ASSETS	$ 11,486,000	$ 4,327,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable-trade	$ 241,000	$ 139,000
Accrued expenses and other current liabilities	798,000	318,000
Current portion of deferred revenue	19,000	--
Current portion of capitalized lease obligation	28,000	--
Total Current Liabilities	1,086,000	457,000
Non current portion of deferred revenue	343,000	--
Non current portion of capitalized lease obligation	34,000	--
Total Liabilities	1,463,000	457,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, $.01 par value:		
Authorized 1,000,000 shares, none issued	--	--
Common stock, $.001 par value:		
Authorized 100,000,000 shares,		
Issued 33,091,467 and 17,972,760 shares at July 31, 2004 and 2003, respectively	33,000	18,000
Additional paid-in capital	34,937,000	22,452,000
Accumulated deficit	(24,941,000)	(18,600,000)
Less: Treasury stock, at cost, 3,012 shares in 2004	(6,000)	--
Total Stockholders' Equity	10,023,000	3,870,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,486,000	$ 4,327,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED JULY 31,
2004 AND 2003

	For The Year Ended 7/31/04	For The Year Ended 7/31/03 As Restated (Note 3)
License Fee	$ 13,000	$ --
Consulting Revenues	453,000	2,000
Total Revenues	466,000	2,000
Research and Development Expenses	2,492,000	1,087,000
Consulting, Selling, General and Administrative Expenses	4,627,000	6,004,000
Total Expenses	7,119,000	7,091,000
Loss From Operations	(6,653,000)	(7,089,000)
Interest Income	98,000	49,000
Loss Before Income Taxes	(6,555,000)	(7,040,000)
Deferred Income Tax Benefit	(214,000)	(84,000)
Net Loss	$ (6,341,000)	$ (6,956,000)
Basic and Diluted Loss Per Common Share	$ (.24)	$ (.45)
Weighted Average Number of Common Shares Outstanding	26,269,000	15,419,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED JULY 31, 2004 AND 2003
AS RESTATED (NOTE 3)

	Common Stock

	Shares	Amount	Additional Paid-in Capital	Accumulate Deficit
BALANCE, July 31, 2002, as previously reported	14,448,817	$ 14,000	$ 13,322,000	$ (9,813,0
Restatement adjustment (Note 3)	--	--	1,831,000	(1,831,0
BALANCE, July 31, 2002, as restated	14,448,817	14,000	15,153,000	(11,644,0
Stock issued in connection with private placements, net of costs	3,200,345	3,000	4,333,000	
Stock issued for options exercised	210,577	--	--	
Stock issued for warrants exercised	113,021	1,000	19,000	
Options issued for services	--	--	1,674,000	
Warrants issued for services	--	--	7,000	
Impact of variable plan accounting	--	--	1,141,000	
Equity investment from related party	--	--	125,000	
Net Loss	--	--	--	(6,956,0
BALANCE, July 31, 2003, as restated	17,972,760	18,000	22,452,000	(18,600,0
Stock issued in connection with private placements, net of costs	13,333,333	14,000	12,771,000	
Stock issued to 2003 private investors in connection with reset provision	1,371,549	1,000	(1,000)	
Stock issued for options exercised	229,719	--	200,000	
Stock issued for warrants exercised	184,106	--	251,000	
Impact of variable plan accounting	--	--	(736,000)	
Net Loss	--	--	--	(6,341,0
BALANCE, JULY 31, 2004	33,091,467	$ 33,000	$ 34,937,000	$(24,941,0

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED JULY 31, 2004 AND 2003

	2004
CASH FLOWS FROM OPERATING ACTIVITIES:	
Net loss	$ (6,341,000)
Adjustments to reconcile net loss to net cash used in operating activities:	
Options issued for services	--
Warrants issued for services	--
Impact of variable plan accounting	(736,000)
Depreciation and amortization	222,000
Allowance for doubtful accounts	--

Changes in operating assets and liabilities:	
Accounts receivable-trade	(128,000)
Prepaid expenses and other current assets	(87,000)
Other assets	6,000
Accounts payable - trade	102,000
Accrued expenses and other current liabilities	480,000
Deferred revenue	362,000
Net cash used in operating activities	(6,120,000)
CASH FLOWS FROM INVESTING ACTIVITIES:	
Purchase of property and equipment	(487,000)
Purchase of investments	(9,560,000)
Maturities of investments	2,042,000
Net cash used in investing activities	(8,005,000)
CASH FLOWS FROM FINANCING ACTIVITIES:	
Proceeds received from issuance of common stock through private placements	12,785,000
Cash received from warrants exercised	251,000
Cash received from options exercised	194,000
Capital contributions from related parties	--
Payments of capitalized lease obligation	(25,000)
Net cash provided by financing activities	13,205,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(920,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,086,000
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 2,166,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:	
Equipment acquired under capitalized lease obligation	$ 87,000
Treasury stock acquired	$ 6,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF THE BUSINESS - NovaDel Pharma Inc. (the "Company"), which was formerly known as Flemington Pharmaceutical Corporation, is incorporated in the State of Delaware. The Company is engaged in the development of novel pharmaceutical products combining presently marketed drugs with patents and pending patents with oral dosage delivery systems of the Company, designed to enhance and accelerate the onset of the therapeutic benefits which the drugs are intended to produce. The Company has entered

into collaboration agreements with other pharmaceutical and veterinary companies for development and marketing its delivery systems.

REVENUES AND COSTS - Consulting revenues from contract clinical research are recognized as earned provided collection is probable. Consulting contract costs normally consist of fees paid to outside clinics for studies and an allocable portion of the Company's operating expenses. General and administrative costs pertaining to contracts are charged to expense as incurred. Revenues from collaboration agreements consist of upfront payments and milestone payments which are initially deferred and subsequently recognized as revenues are earned. Such agreements have costs consisting of operating costs for goods and services required to meet obligations under the collaboration agreements which are charged to expense as incurred.

CASH EQUIVALENTS AND INVESTMENTS - Cash equivalents include certificates of deposit and money market instruments purchased with original maturities of three months or less when purchased. Short-term investments with original maturities greater than three months and less than one year and long-term investments with maturities greater than one year consist of certificates of deposit are valued at cost which approximates fair market value.

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

PROPERTY AND EQUIPMENT - Property and equipment, including leasehold improvements, are stated at cost. The Company provides for depreciation and amortization using the straight-line method, based upon estimated useful lives of five to 10 years or the lease term, if shorter.

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

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

DEFINED CONTRIBUTION RETIREMENT PLANS - During January 2004, the Company established a 401(k) retirement plan, available to all employees and requiring contributions by the Company. During the year ended July 31,

2004, the Company contributed approximately $56,000 to this plan. Prior to January 2004, the Company had a Simple IRA retirement plan, available to all employees and providing for contributions at management's discretion. During the years ended July 31, 2004 and 2003, the Company made contributions to this Simple IRA of approximately $37,000 and $15,000, respectively.

USE OF ESTIMATES - The preparation of financial statements in conformity with accounting principles generally accepted in the United States, require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

EARNINGS (LOSS) PER SHARE - Statement of Financial Accounting Standards (FAS) No. 128, "Earnings Per Share" requires the disclosure of both basic and diluted earnings (loss) per share. Basic earnings (loss) per share is based on the weighted average of all common shares outstanding. The computation of diluted earnings (loss) per share does not assume the conversion, exercise or contingent issuance of potentially dilutive securities that would have an antidilutive effect. The amount of potentially dilutive securities includes options and warrants exercisable for 20,044,000 shares of common stock at July 31, 2004 and 18,766,000 shares of common stock at July 31, 2003.

STOCK-BASED COMPENSATION - The Company follows the intrinsic value method of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options. Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123) permits a company to elect to follow the intrinsic value method of APB 25 rather than the alternative fair value accounting provided under FAS 123, but requires pro forma net income (loss) and earnings (loss) per share disclosures as well as various other disclosures not required under FAS 123 for companies following APB 25. The Company has adopted the disclosure provisions required under Financial Accounting Standards Board Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" (FAS 148). Because the exercise price of the Company's stock options equals the market price of the underlying stock on the date of grant, no compensation expense is initially recognized under APB 25. The Registrant, its Audit Committee and its current and former independent registered public accounting firms have agreed that certain of the Company's issued and outstanding stock options that permit cashless exercise should be subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expenses should be recognized in the Company's previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation-an interpretation of APB No. 25" (Issue Date 3/00). Accordingly, management has restated the Company's financial statements for the first three quarters of fiscal 2004, the interim periods of fiscal 2003 and 2002, and for the fiscal years 2003 and 2002. This report contains restated financial information for all of the above fiscal periods. The reasons for, and financial impact of, the adjustments are

described in Note 3.

The fair values of options granted in 2004 and 2003 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company's common stock of 56% in 2004 and 74% in 2003, and an expected life of the options of six years and five years in 2004 and 2003, respectively.

If the Company had elected to recognize compensation cost for all outstanding options granted by the Company to employees by applying the fair value recognition provisions of FAS No. 123 to stock-based employee compensation using the Black Scholes option pricing model, net loss and net loss per share would have been increased or decreased to the pro forma amounts indicated below:

	Ye
	2004
Net loss - basic and diluted, as reported	$(6,341,
Compensation expense (credit) resulting from variable plan accounting	(736,
Total stock-based employee compensation expense using the fair value based method for all awards	(795,
Pro forma	$(7,872,
Basic and diluted net loss per common share:	
As reported	$ (
Pro forma	$ (

NOTE 2 - LIQUIDITY

The Company has reported a net loss of $6,341,000 for the year ended July 31, 2004 and a net loss of $6,956,000 for the year ended July 31, 2003 as restated (see Note 3). Management believes that the Company will continue to incur net losses through at least July 31, 2005. Based on the Company's resources available at July 31, 2004, management believes these resources are adequate to fund the operations through at least July 31, 2005. As of July 31, 2004, the Company had working capital of $7,676,000, cash and cash equivalents of $2,166,000 and short term investments of $6,211,000. Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long

term liquidity is contingent upon achieving sales and/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.

NOTE 3 - RESTATEMENT OF FINANCIAL STATEMENTS

In connection with the preparation of the Annual Report on Form 10-KSB of the Company for the fiscal year ended July 31, 2004, the Company's independent registered public accounting firm brought to the attention of the Company that certain of the Company's issued and outstanding stock options are subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expenses should be recognized in the Company's previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation-an interpretation of APB Opinion No. 25" (Issue Date 3/00). After reviewing the matter with its current and former independent registered public accounting firms, the Company has identified certain adjustments that necessitate the restatement of its financial statements for the first three quarters of fiscal 2004, the interim periods of fiscal 2003 and 2002, and for the fiscal years 2003 and 2002.

These adjustments reflect variable plan accounting treatment of the affected stock options for the relevant periods, resulting from cashless exercise provisions applicable to options held by employees and directors. Under variable plan option accounting, compensation expense is increased or decreased as a result of changes in the market price of the Company's common stock.

The restatement adjustments to the Company's financial statements for the years ended July 31, 2003 and 2002, respectively, are summarized as follows:

RESTATED BALANCE SHEETS
AS OF JULY 31, 2003 AND 2002

	As Previously Reported 7/31/03	Restatement Adjustment 7/31/03	As Restated 7/31/03	As Previou Reported 7/31/02
ASSETS				

CURRENT ASSETS:				
Cash and cash equivalents	$ 3,086,000	$ --	$ 3,086,000	$ 3,314,0
Accounts receivable - trade	2,000	--	2,000	1,0
Prepaid expenses and other current assets	168,000	--	168,000	96,0
Total Current Assets	3,256,000	--	3,256,000	3,411,0
Property and Equipment, net	714,000	--	714,000	406,0
OTHER ASSETS	357,000	--	357,000	22,0
TOTAL ASSETS	$ 4,327,000	$ --	$ 4,327,000	$ 3,839,0
CURRENT LIABILITIES:				
Accounts payable-trade	$ 139,000	$ --	$ 139,000	$ 125,0
Accrued expenses and other current liabilities	318,000	--	318,000	191,0
Total Liabilities	457,000	--	457,000	316,0
COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY:				
Preferred stock	--	--	--	
Common stock	18,000	--	18,000	14,0
Additional paid-in capital	19,480,000	2,972,000	22,452,000	13,322,0
Accumulated deficit	(15,628,000)	(2,972,000)	(18,600,000)	(9,813,0
Total Stockholders' Equity	3,870,000	--	3,870,000	3,523,0
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,327,000	$ --	$ 4,327,000	$ 3,839,0

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

RESTATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED JULY 31, 2003 AND 2002

	For The Year Ended 7/31/03 As Previously Reported	For The Year Ended 7/31/03 Restatement Adjustment	For The Year 7/31/03 As Restated	For The Ye 7/31/02 As Previous Reported

LICENSE FEE	$ --	$ --	$ --	$ -
CONSULTING REVENUES	2,000	--	2,000	339,00
TOTAL REVENUES	2,000	--	2,000	339,00
RESEARCH AND DEVELOPMENT EXPENSES	1,048,000	39,000	1,087,000	962,00
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,902,000	1,102,000	6,004,000	3,799,00
TOTAL EXPENSES	5,950,000	1,141,000	7,091,000	4,761,00
LOSS FROM OPERATIONS	(5,948,000)	(1,141,000)	(7,089,000)	(4,422,00
INTEREST INCOME	49,000	--	49,000	44,00
LOSS BEFORE INCOME TAXES	(5,899,000)	(1,141,000)	(7,040,000)	(4,378,00
DEFERRED INCOME TAX BENEFIT	(84,000)	--	(84,000)	(88,00
NET LOSS	$ (5,815,000)	$ (1,141,000)	$ (6,956,000)	$ (4,290,00
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.38)	$ (0.07)	$ (0.45)	$ (0.3
WEIGHTED-AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	15,419,000	15,419,000	15,419,000	11,361,00

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment are summarized as follows:

	July 31, 2004	July 31, 2003
Equipment	$ 303,000	$ 713,000
Furniture and fixtures	1,054,000	122,000
Leasehold improvements	184,000	131,000
	1,541,000	966,000
Less: Accumulated depreciation and amortization	475,000	252,000

$1,066,000	$714,000

NOTE 5 - RELATED PARTY TRANSACTIONS

LEGAL FEES - The Company has incurred legal fees charged by a former officer and director of the Company. These fees approximated $195,000 and $160,000 for the years ended July 31, 2004 and 2003, respectively.

CONSULTING AGREEMENT - Mr. John H. Klein's, the former Chairman of the Company's Board of Directors, consulting agreement ceased on January 31, 2004. During fiscal 2004, we paid Mr. Klein, our former Chairman of the Board, approximately $186,000, and we paid him approximately $300,000 for fiscal 2003, pursuant to our consulting agreement with Mr. Klein (including finder fees relating to the Company's licensing agreements). The amount of the fees is determined according to the net revenue received by us in connection with the Par Pharmaceutical agreement. The amount of fees paid to Mr. Klein will fluctuate over the term of the agreement, primarily dependent on the amount of milestone payments received by the Company. 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.

LICENSE AGREEMENTS WITH RELATED PARTIES (SEE NOTE 7) - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. (Manhattan) for the worldwide, exclusive rights to the Company's proprietary lingual spray technology to deliver propofol for pre-procedural sedation.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera Pharmaceuticals, Inc. (Velcera), a veterinary company.

The license agreement is for the exclusive rights to the Company's proprietary lingual spray technology in animals.

In October 2004, the Company entered into a license and development agreement with Hana Biosciences, Inc. (Hana) to develop and market the Company's lingualspray version of ondansetron. The agreement is an exclusive license for the United States and Canada.

Lindsay A. Rosenwald, M.D., a significant stockholder of the Company, may be deemed to be an affiliate of the Company, Manhattan, Velcera, and Hana. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to the Company's agreements with the parties to such agreements from time to time.

NOTE 6 - STOCKHOLDERS' EQUITY

PRIVATE PLACEMENTS:

In January 2004, the Company completed a private placement and received net proceeds of $12,785,000 from the sale of a total of 140 units of the Company's securities. Each unit consisted of 95,238 common shares, par

value $.001, and 28,571 warrants. Each warrant entitles the holder to purchase an additional share of the Company's common stock at an exercise price of $1.40 within five years. The sale price of each unit was $100,000. A total of 13,333,333 shares and approximately 4,000,000 warrants were issued.

The securities were sold through Paramount Capital, Inc. (Paramount), a NASD broker-dealer. For its services as placement agent, the Company paid Paramount a commission of 7% of the aggregate amount raised and also issued to Paramount (and its designees) unit purchase options to purchase 1,330,303 shares of common stock at an exercise price of $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. A significant stockholder of the Company is a controlling principal of Paramount.

In May 2003, the Company completed a private placement and received net proceeds of approximately $4,336,000 from the placement of a total of 48.01 units of the Company's securities. Each unit consisted of 66,666-2/3 common shares, par value $.001, and 16,666-2/3 warrants. Each warrant entitles the holder to purchase an additional share of the Company's common stock at an exercise price

of $2.00 within five (5) years. The sale price of each unit was $100,000 ($1.50 per share). In connection with the Company's May 2003 private placement, the Company had agreed, for a period of one year, that if the Company issued shares of common stock at a par share price less than $1.50 (the price per share in such offering) that such investors would receive "reset price" shares without any additional consideration being paid to the Company (so that those investors would receive additional shares as if they purchased their shares at such lower per share purchase price). The per share sale price of the January 2004 offering triggered the reset rights of such investors and 1,371,549 shares of common stock were issued to these investors for no additional consideration. The reset provisions expire in May 2004.

PREFERRED STOCK - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of such Preferred Stock has been designated or issued through July 31, 2004. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion rights, voting, terms of redemption and liquidation.

NOTE 7 - COMMITMENTS AND CONTINGENCIES

EMPLOYMENT AND CONSULTING AGREEMENTS - At July 31, 2004, the Company had employment agreements with six officers of the Company providing for an aggregate annual salary of $1,356,000.

Each of these employment agreements has a three year term. They are due to expire on the following schedule: Dr. Dugger's agreement in January 2005, Dr. Shangold's agreement in December 2005, Mr. Cohen's agreement in May

2006, Dr. El Shafy's agreement in January 2007, and Ms. Frydman's agreement in May 2007. Mr. Deitman resigned from his position as Chief Financial Officer on September 30, 2004. The employment agreements of Dr. Shangold, Dr. El Shafy and Mr. Cohen automatically extend for additional one-year periods unless either party to the agreement advises the other to the contrary in writing at least 90 days prior to the expiration of their term.

All of the foregoing employment agreements provide for the issuance of bonuses based on certain factors. The agreements with Dr. Shangold, Ms. Frydman, Dr. El Shafy and Mr. Cohen provide for the grant of options to purchase shares of the Company's common stock, vesting ratably over the term of the agreement.

Additionally, at July 31, 2004, the Company had a consulting agreement with Robert C. Galler providing for an annual salary of $180,000. The agreement terminates in February 2005.

LICENSE AND DEVELOPMENT AGREEMENTS - In April 2003, the Company entered into a license and development agreement with Manhattan for the worldwide, exclusive rights to the Company's proprietary lingual spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first $125,000 of which was partially received during June 2003. During the year ended July 31, 2004, the Company invoiced Manhattan approximately $400,000 for the Company's reimbursable expenses. 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.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's propriety lingual spray technology in animals. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement.

In July 2004, the Company entered into a licensing agreement with Par Pharmaceutical, Inc. (Par Pharmaceutical) for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the United States and Canada. The Company has received $250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement.

In October 2004, the Company entered into a license and development agreement with Hana to develop and market the Company's lingual spray version of ondansetron. The agreement is an exclusive license for the United States and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana purchased 400,000 shares of Company common

stock at a per share price of $2.50. Hana issued to the Company $500,000 of common stock of Hana (73,121 shares at $6.84 per share) for no additional consideration. The proceeds received from Hana will be included in deferred revenue and recognized over the period of the development agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement.

LEASES - In August 2000, the Company entered into a five-year lease agreement, effective October 2000, for approximately 4,500 square feet of office, laboratory and manufacturing space. Annual rent is approximately $63,000 plus real estate taxes, currently estimated to be approximately $11,000 annually.

In March 2003, the Company entered into a 10-year lease for approximately 31,500 square feet of office, laboratory, manufacturing and warehouse space. During the first five years of the lease, the annual rent is approximately $332,000 plus a proportionate share of real estate taxes and common areas. Beginning in the sixth year and continuing through the tenth year of the lease, the annual rent will be approximately $365,000 plus a proportionate share of real estate taxes and common areas.

Future minimum rental payments subsequent to July 31, 2004 are as follows:

Years Ending July 31,	
2005	$506,000
2006	$443,000
2007	$476,000
2008	$476,000
2009	$476,000
Thereafter	$476,000
	$2,853,000

NOTE 8 - INCOME TAXES

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

	Year ended July 31	
	2004	2003 As Restated
Net operating loss carryforwards	$ 8,001,000	$ 5,300,000
Valuation allowance	(8,001,000)	(5,300,000)
Net deferred tax asset	$ --	$ --

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

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

	Year ended July 31	
	2004	2003 As Restated (Note 3)
Federal tax at statutory rate of 34%.....	$(2,228,000)	$(2,393,000)
State income tax	(393,000)	(422,000)
Non deductible options issued for services	(294,000)	1,126,000
Sale of net operating losses	(214,000)	(84,000)
Increase in valuation allowance	2,915,000	1,689,000
	$ (214,000)	$ (84,000)

At July 31, 2004, the Company has federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately $23,029,000 and $13,648,000, respectively, which can be used to offset current and future taxable income, if any, through 2024. The Company has provided valuation allowances to offset its deferred tax assets due to the significant uncertainties related to its ability to generate future taxable income.

During December 2003, the Company received approximately $214,000 as consideration for transferring approximately $2,854,000 of New Jersey net operating loss tax benefits to a third party corporation buyer. During December 2002, the Company received approximately $84,000 from this program.

NOTE 9 - STOCK OPTIONS

At July 31, 2004, the Company had three plans which allow for the issuance of stock options and other awards, the 1992 Stock Option Plan, the 1997 Stock Option Plan and the 1998 Stock Option Plan (the Plans). The total number of shares of common stock reserved for issuance, either as incentive stock options (ISOs) under the Internal Revenue Code or as non-qualified options, under the 1992 and 1997 Plans is 500,000 shares each and 1,829,500 under the 1998 Plan. ISOs may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company's common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years.

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

The Plans had provisions that permitted the cashless exercise of stock options. The accompanying restated financial statements reflect the use of variable plan accounting for such options (see Note 3). The Company's Board of Directors rescinded the cashless exercise provisions for all outstanding options in October 2004, and variable plan accounting will not be required after the quarter ended October 31, 2004.

At July 31, 2004, there were 4,618,000 non-plan options reserved for issuance.

Information with respect to stock option activity is as follows (in thousands, except exercise price amounts):

	Outstanding Options	
	Number of Options	Weighted Average Exercise Price
Balance at August 1, 2002	4,478	$1.61
Additional Shares reserved	--	--
Grants	2,159	1.60
Exercises	445	.94
Cancellation	--	--
Balance at July 31, 2003	6,192	$1.66
Additional Shares reserved	--	$-
Grants	1,308	1.75
Exercises	260	.99
Cancellations	1,195	2.31
Balance at July 31, 2004	6,045	$1.60

The following table summarizes information related to options outstanding at July 31, 2004:

RANGE OF EXERCISE PRICES	Outstanding Options			Options
	Options 000's	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options 000's
$0.01 - $1.00.....	1,775	5.9	$ .73	1,775
$1.01 - $2.00.....	3,373	4.8	1.77	1,949
$2.01 - $3.00.....	497	7.7	2.34	363
$3.01 - $4.00.....	400	7.8	3.12	350
	6,045	6.5	$1.60	4,437

NOVADEL PHARMA INC.
NOTES TO FINANCIAL STATEMENTS

The following table summarizes information related to warrants outstanding at July 31, 2004:

PRICE RANGE	NUMBER OUTSTANDING	REMAINING CONTRACTUAL LIFE (YEARS)
$0.01-1.00	7,343,140	5.40
$1.01-1.99	6,556,397	3.95
$2.00	100,004	3.28
Totals	13,999,541	

RESTATEMENT OF QUARTERLY DATA (UNAUDITED)

In connection with the preparation of the Annual Report on Form 10-KSB of the Company for the fiscal year ended July 31, 2004, the Company's independent registered public accounting firm brought to the attention of the Company that certain of the Company's issued and outstanding stock options are subject to variable plan accounting treatment under applicable accounting standards, and, accordingly, previously unrecognized compensation expenses should be recognized in the Company's previously issued financial statements under the Financial Accounting Standards Board's Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation-an interpretation of APB Opinion No. 25" (Issue Date 3/00). After reviewing the matter with its current and former independent registered public accounting firms, the Company has identified certain adjustments that necessitate the restatement of its financial statements for the first three quarters of fiscal 2004, the interim periods of fiscal 2003 and 2002, and for the fiscal years 2003 and 2002 (see Note 3 to financial statements).

These adjustments reflect variable plan accounting treatment of the affected stock options for the relevant periods, resulting from cashless exercise provisions applicable to options held by employees and directors. Under variable plan option accounting, compensation expense is increased or decreased as a result of changes in the market price of the Company's common stock.

The following table shows the effects of the restatement on the Company's quarterly results of operations. In the tables that follow, the columns labeled "Restatement Adjustments" represent adjustments for compensation expense (credit) previously not recognized.

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NOVADEL PHARMA INC.
RESTATED STATEMENT OF OPERATIONS
FOR THE QUARTER ENDED APRIL 30, 2004

	As Previously Reported For The Qtr Ended 4/30/04	Restatement Adjustment For The Qtr Ended 4/30/04	As Restated For The Qtr Ended 4/30/04
LICENSE FEE	$ 5,000	$ --	$ 5,000
CONSULTING REVENUES	11,000	--	11,000
TOTAL REVENUES	16,000	--	16,000
RESEARCH AND DEVELOPMENT EXPENSES	587,000	(6,000)	581,000
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,218,000	(193,000)	1,025,000
TOTAL EXPENSES	1,805,000	(199,000)	1,606,000
LOSS FROM OPERATIONS	(1,789,000)	199,000	(1,590,000)
INTEREST INCOME	59,000	--	59,000
LOSS BEFORE INCOME TAXES	(1,730,000)	199,000	(1,531,000)
DEFERRED INCOME TAX BENEFIT	--	--	--
NET LOSS	$ (1,730,000)	$ 199,000	$ (1,531,000)
BASIC LOSS PER COMMON SHARE	$ (0.05)	$ 0.00	$ (0.05)
SHARES USED IN COMPUTATION OF BASIC LOSS PER COMMON SHARE	32,866,531	32,866,531	32,866,531

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NOVADEL PHARMA INC.
RESTATED STATEMENTS OF OPERATIONS
FOR THE QUARTERS ENDED JANUARY 31, 2004 AND OCTOBER 31, 2003

	As Previously Reported For The Qtr Ended 1/31/04	Restatement Adjustment For The Qtr Ended 1/31/04	As Restated For The Qtr Ended 1/31/04	As Previously Reported For The Qtr Ended 10/31/03
LICENSE FEE	$ 3,000	$ --	$ 3,000	$ --
CONSULTING REVENUES	18,000	--	18,000	--
TOTAL REVENUES	21,000	--	21,000	--
RESEARCH AND DEVELOPMENT EXPENSES	389,000	(3,000)	386,000	--
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,265,000	(72,000)	1,193,000	1,733,000
TOTAL EXPENSES	1,654,000	(75,000)	1,579,000	1,733,000
LOSS FROM OPERATIONS	(1,633,000)	75,000	(1,558,000)	(1,733,000)
INTEREST INCOME	5,000	--	5,000	6,000
LOSS BEFORE INCOME TAXES	(1,628,000)	75,000	(1,553,000)	(1,727,000)
DEFERRED INCOME TAX BENEFIT	(214,000)	--	(214,000)	--
NET LOSS	$ (1,414,000)	$ 75,000	$ (1,339,000)	$ (1,727,000)
BASIC LOSS PER COMMON SHARE	$ (0.06)	$ 0.00	$ (0.06)	$ (0.10)
SHARES USED IN COMPUTATION OF BASIC LOSS PER COMMON SHARE	23,247,336	23,247,336	23,247,336	17,972,760

NOVADEL PHARMA INC.
RESTATED STATEMENTS OF OPERATIONS
FOR THE QUARTERS ENDED JULY 31, 2003 AND APRIL 30, 2003

	As Previously Reported For The Qtr Ended	Restatement Adjustment For The Qtr Ended	As Restated For The Qtr Ended	As Previou Reported For The Q Ended

	7/31/03	7/31/03	7/31/03	4/30/03
LICENSE FEE	$ --	$ --	$ --	$
CONSULTING REVENUES	2,000	--	2,000	
TOTAL REVENUES	2,000	--	2,000	
RESEARCH AND DEVELOPMENT EXPENSES	1,048,000	16,000	1,064,000	264,0
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	424,000	1,437,000	1,861,000	614,0
TOTAL EXPENSES	1,472,000	1,453,000	2,925,000	878,0
INCOME (LOSS) FROM OPERATIONS	(1,470,000)	(1,453,000)	(2,923,000)	(878,0
INTEREST INCOME	9,000	--	9,000	7,0
INCOME (LOSS) BEFORE INCOME TAXES	(1,461,000)	(1,453,000)	(2,914,000)	(871,0
DEFERRED INCOME TAX BENEFIT	(84,000)	--	(84,000)	
NET INCOME (LOSS)	$ (1,377,000)	$ (1,453,000)	$ (2,830,000)	$ (871,0
BASIC INCOME (LOSS) PER COMMON SHARE	$ (0.09)	$ (0.09)	$ (0.18)	$ (0.
SHARES USED IN COMPUTATION OF BASIC INCOME (LOSS) PER COMMON SHARE	15,419,000	15,419,000	15,419,000	15,155,6

NOVADEL PHARMA INC.
RESATED STATEMENTS OF OPERATIONS
FOR THE QUARTERS ENDED JANUARY 31, 2003 AND OCTOBER 31, 2002

	As Previously Reported For The Qtr Ended 1/31/03	Restatement Adjustment For The Qtr Ended 1/31/03	As Restated For The Qtr Ended 1/31/03	As Previously Reported For The Qtr Ended 10/31/02
LICENSE FEE	$ --	$ --	$ --	$ --

CONSULTING REVENUES	--	--	--	--
TOTAL REVENUES	--	--	--	--
RESEARCH AND DEVELOPMENT EXPENSES	348,000	56,000	404,000	--
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,523,000	2,413,000	3,936,000	1,729,000
TOTAL EXPENSES	1,871,000	2,469,000	4,340,000	1,729,000
LOSS FROM OPERATIONS	(1,871,000)	(2,469,000)	(4,340,000)	(1,729,000)
INTEREST INCOME	18,000	--	18,000	15,000
LOSS BEFORE INCOME TAXES	$ (1,853,000)	$ (2,469,000)	$ (4,322,000)	$ (1,714,000)
DEFERRED INCOME TAX BENEFIT	(84,000)	--	(84,000)	--
NET LOSS	$ (1,769,000)	$ (2,469,000)	$ (4,238,000)	$ (1,714,000)
BASIC LOSS PER COMMON SHARE	$ (0.12)	$ (0.17)	$ (0.29)	$ (0.12)
SHARES USED IN COMPUTATION OF BASIC LOSS PER COMMON SHARE	14,542,821	14,542,821	14,542,821	14,509,523

NOVADEL PHARMA INC.
RESTATED STATEMENTS OF OPERATIONS
FOR THE QUARTERS ENDED JULY 31, 2002 AND APRIL 30, 2002

	As Previously Reported For The Qtr Ended 7/31/02	Restatement Adjustment For The Qtr Ended 7/31/02	As Restated For The Qtr Ended 7/31/02	As previo Reported For The Q Ended 4/30/02
LICENSE FEE	$ --	$ --	$ --	$
CONSULTING REVENUES	4,000	--	4,000	81,0
TOTAL REVENUES	4,000	--	4,000	81,0

RESEARCH AND DEVELOPMENT EXPENSES	962,000	(154,000)	808,000	
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	756,000	(5,126,000)	(4,370,000)	2,139,0
TOTAL EXPENSES	1,718,000	(5,280,000)	(3,562,000)	2,139,0
INCOME (LOSS) FROM OPERATIONS	(1,714,000)	5,280,000	3,566,000	(2,058,0
INTEREST INCOME	12,000	--	12,000	17,0
INCOME (LOSS) BEFORE INCOME TAXES	(1,702,000)	5,280,000	3,578,000	(2,041,0
DEFERRED INCOME TAX BENEFIT	--	--	--	
NET INCOME (LOSS)	$ (1,702,000)	$ 5,280,000	$ 3,578,000	$ (2,041,0
BASIC INCOME (LOSS) PER COMMON SHARE	$ (0.15)	$ 0.46	$ 0.31	$ (0.
SHARES USED IN COMPUTATION OF BASIC INCOME (LOSS) PER COMMON SHARE	11,361,000	11,361,000	11,361,000	13,432,7

NOVADEL PHARMA INC.
RESTATED STATEMENT OF OPERATIONS
FOR THE QUARTER ENDED JANUARY 31, 2002

	As Previously Reported For The Qtr Ended 1/31/02	Restatement Adjustment For The Qtr Ended 1/31/02	As Restated For The Qtr Ended 1/31/02
LICENSE FEE	$ --	$ --	$ --
CONSULTING REVENUES	183,000	--	183,000
TOTAL REVENUES	183,000	--	183,000
RESEARCH AND DEVELOPMENT EXPENSES	--	89,000	89,000
CONSULTING, SELLING, GENERAL AND			

ADMINISTRATIVE EXPENSES	548,000	3,471,000	4,019,000
TOTAL EXPENSES	548,000	3,560,000	4,108,000
LOSS FROM OPERATIONS	(365,000)	(3,560,000)	(3,925,000)
BUY-OUT OF CONSULTANT'S CONTRACT	(33,000)	--	(33,000)
INTEREST INCOME	10,000	--	10,000
LOSS BEFORE INCOME TAXES	(388,000)	(3,560,000)	(3,948,000)
DEFERRED INCOME TAX BENEFIT	(88,000)	--	(88,000)
NET LOSS	$ (300,000)	$(3,560,000)	$(3,860,000)
BASIC LOSS PER COMMON SHARE	$ (0.03)	$ (0.36)	$ (0.39)
SHARES USED IN COMPUTATION OF BASIC LOSS PER COMMON SHARE	9,942,291	9,942,291	9,942,291

INDEX TO EXHIBITS

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

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
3.1	Restated Certificate of Incorporation of the Company	Incorporated by reference to Ex Company's Quarterly Report on F with the SEC on June 14, 2004
3.2	Amended and Restated By-laws of the Company	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on August 8, 333-33201)
4.1	Form of Class C Warrant for the Purchase of Shares of Common Stock	Incorporated by reference to Ex Company's Current Report on For the SEC on January 12, 2004
10.1	*1992 Stock Option Plan	Incorporated by reference to th Registration Statement on Form the SEC on August 8, 1997 (File
10.2	*Form of Incentive Stock Option Agreement	Incorporated by reference to th

	under the 1992 Stock Option Plan	Registration Statement on Form the SEC on August 8, 1997 (File
10.3	*1997 Stock Option Plan	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on August 8, 333-33201)
10.4	*Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan	Incorporated by reference to th Registration Statement on Form the SEC on August 8, 1997 (File

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
10.5	*1998 Stock Option Plan	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on June 18, 333-116665)
10.6	*Form of Stock Option Agreement under the 1998 Stock Option Plan	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on June 18, 333-116665)
10.7	*Form of Nonqualified Stock Option Agreement	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on June 18, 333-116665)
10.8	Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers	Incorporated by reference to Ex Schedule 13D as filed by Lindsa the SEC on December 21, 2001
10.9	Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on April 15, 333-86262)
10.10	Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C.	Incorporated by reference to Ex Company's Quarterly Report on F period ended April 30, 2003, as on June 19, 2003
10.11	Form of Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003	Incorporated by reference to Ex Company's Quarterly Report on F period ended April 30, 2003, as on June 19, 2003
10.12	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Ex Amendment No. 1 to the Company' Form 10-KSB, as filed with the

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
10.13	Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc.	Filed herewith
10.14	Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc.	Filed herewith
10.15	*Employment Agreement, dated as of January 1, 2002, between the Company and Harry A. Dugger III, Ph.D.	Incorporated by reference to Ex Company's Registration Statemen filed with the SEC on April 15, 333-86262)
10.16	*Employment Agreement, dated as of December 3, 2002, by and between the Company and Gary Shangold	Incorporated by reference to Ex Company's Quarterly Report on F period ending January 31, 2003, SEC on March 10, 2003
10.17	*Amendment Number 1, dated December 22, 2002, to the Employment Agreement dated December 3, 2002, between the Company and Gary Shangold	Incorporated by reference to Ex Company's Quarterly Report on F period ending January 31, 2003, SEC on March 10, 2003
10.18	*Employment Agreement, dated as of May 23, 2003, by and between the Company and Barry Cohen	Incorporated by reference to Ex Company's Quarterly Report on F period ended April 30, 2003, as on June 19, 2003
10.19	*Amendment to Mohammed Abd El-Shafy Employment Agreement, dated as of April 9, 2004, between the Company and Mohammed Abd El-Shafy, Ph.D.	Incorporated by reference to Ex Company's Quarterly Report on F with the SEC on June 14, 2004
10.20	*Employment Agreement, dated as of April 9, 2004, by and between the Company and Jean Frydman	Filed herewith

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
23.1	Consent of J.H. Cohn LLP	Filed herewith
23.2	Consent of Wiss & Company, LLP	Filed herewith

31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	Filed herewith
31.2	Certification of Interim Principal Financial Officer under Rule 13a-14(a)	Filed herewith
32	Certifications of the Chief Executive Officer and Interim Principal Financial Officer under 18 USC 1350	Filed herewith