NOVADEL PHARMA INC
Form 10KSB
October 29, 2003

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark One)

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

For the fiscal year ended July 31, 2003

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)

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

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
Redeemable Common Stock Purchase Warrants

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. [X].

State the issuer's revenues for its most recent fiscal year: $2,000

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant at October 27, 2003 was approximately $ 19,027,000 based upon the closing sale price of $2.01 for the Registrant's Common Stock, $.001 par value, as reported by the National Association of Securities Dealers OTC Bulletin Board on October 27, 2003.

As of October 27, 2003 the Registrant had 17,972,760 shares of Common Stock, $.001 par value, outstanding.

Documents incorporated by reference: None

NOVADEL PHARMA INC.

Annual Report on Form 10-KSB
For the Fiscal Year Ended July 31, 2003

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PART I

ITEM 1. BUSINESS.

General

NovaDel Pharma Inc. (formerly known as Flemington Pharmaceutical Corporation), is engaged in the development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs. Our (both patented and patent-pending) delivery systems are lingual sprays, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system enhances and greatly accelerates the onset of the therapeutic benefits which the drugs are intended to produce, to provide therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on drugs which are already available and proven in the marketplace. In addition to increasing bioavailability by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary delivery system offers the following significant advantages: (i) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (ii) improved dosage reliability; (iii) allowing medication to be taken without water; and (iv) improved patient convenience and compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we will seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. Due to our small revenue base, low level of working capital and the inability to conclude development agreements with major pharmaceutical companies, we have been unable aggressively to pursue our product development strategy. We will require significant additional financing and/or a strategic alliance with a well-funded development partner to undertake our business plan. See "Management Discussion and Analysis."

At its inception in 1982, Novadel, then known as Pharmaconsult, was a consultant to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992 NovaDel has used its consulting revenues to fund its 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. The Company's principal business address is 25 Minneakoning Road,, Flemington, New Jersey, 08822, and its telephone number is (908) 782-3431.

Safe harbor statements under the private securities litigation reform act of 1995

This Annual Report includes "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. The safe harbor provisions of the Securities Exchange Act of 1934 and the Securities Act of 1933 apply to forward-looking statements made by us. These statements can be

identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," "plans," "future," "intends," "continue," "estimate" or "anticipates" or the negatives or variations of these terms, and other comparable terminology. In addition, any statements discussing strategy that involve risks and uncertainties are forward-looking.

Forward-looking statements involve risks and uncertainties, including those risks and uncertainties identified in, or incorporated by reference into, this report. Due to these risks and uncertainties, the actual results that we achieve may differ materially from these forward-looking statements. These forward-looking statements are based on current expectations, and we assume no obligation to update this information. In preparing this report, we may have made a number of assumptions and projections about the future of our business. These assumptions and projections could be wrong for several reasons including, but not limited to, those factors identified in the "Risk Factors" section, below.

You are urged to carefully review and consider the various disclosures that we make in this report .These disclosures attempt to advise interested parties of the risk factors that may affect our business and the market price of our shares of common stock.

Recent Developments - Private Placement.

In April and May 2003, we sold Units (consisting of common stock and warrants) to accredited investors on a private placement basis. Investors were issued one warrant for each four shares purchased. An aggregate of 3,200,345 shares of common stock and warrants for 800,095 shares were sold to the investors. The warrants are exercisable for five years, at an exercise price of $2.00 per share. The securities were sold through Paramount Capital, Inc., a NASD broker-dealer. The gross proceeds of the private offering were approximately $4.8 million. For its services as placement agent, we paid Paramount a 7.5% commission fee of the aggregate amount raised (approximately $360,000) and also issued to Paramount warrants to purchase 160,017 shares of common stock at an exercise price of $1.65 and 40,004 shares of common stock at an exercise price of $2.00. In connection with the offering, we agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the shares of common stock and the shares underlying the warrants (as well as the shares underlying Paramount's warrants). We also agreed that if, at any time following the closing of the offering and continuing for a period of two (2) years thereafter, we offer shares of our common stock for sale in a capital raising transaction, we will permit the investors to purchase such number of shares of common stock to maintain their pro rata ownership percentages of NovaDel. We also agreed that if, at any time following the closing of the offering for a period of one year, we sold shares of common stock in a capital raising transaction (of at least $1 million) at a per share price less than $1.50, we will issue to the investors additional shares of common stock (so that they would receive their original shares at such lower price). See "Certain Relationships and Related Transactions".

Product Development

Cardiovascular (Nitroglycerin)

NovaDel's Nitroglycerin product has been formulated and stability testing has been completed. A United States patent was issued in 1999. An IND was filed with FDA in early 2002 and clinical trials began in July 2002 and were completed in December 2002. NovaDel anticipates filing an NDA in the fourth quarter of 2003.

Loratadine Lingual Spray

A loratadine lingual spray formulation has been developed and successfully undergone stability testing. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was prepared. An IND was filed and a pharmacokinetic study was carried out under this IND to compare the plasma levels following administration of a 5.0 mg and a 2.5 mg lingual spray to those after administration of a 10 mg tablet. Both lingual spray doses resulted in higher plasma levels concentrations than the 10 mg tablet. In the case of the 5.0 mg dose the peak plasma levels were greater than twice those of the tablet and those after the 2.5 mg dose were about 50% higher. Therapeutic plasma levels based on the claimed start of antihistaminic effect for the Claritin(R) tablet (1-3 hours) were achieved between 24 and thirty minutes. Subsequently, a "wheal and flare" study was completed, the results of which are currently being evaluated. NovaDel is presently seeking a partner to complete development of this product.

Clemastine Lingual Spray

The formulation of clemastine lingual spray that was terminated by Novartis in 1998 was revised and a Pre-IND meeting with FDA was held in the third quarter of 2000. Based on the results of that meeting a plan for further development was prepared and an IND was filed. A pilot nasal challenge efficacy study was initiated in the second 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, the results appear to support the concept that a clemastine lingual spray could be a 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 pharmacokinetic dose-ranging study has been completed and other pilot studies are planned. NovaDel is seeking a partner to complete development of this product.

Estradiol Sprays

NovaDel presently has two open IND's for the study of Estradiol therapies and has performed pharmacokinetic studies. Due to questions that recently have been raised about estrogen therapy, NovaDel is reevaluating the viability of this development program.

Agreement with Manhattan Pharmaceuticals

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. (Manhattan) for the worldwide, exclusive rights

to our lingual spray technology to deliver Propofol for pre-procedural sedation. The terms of the agreement call for certain milestones and other payments, the first of which was received during June 2003. One of the Company's Affiliates, Dr. Lindsay Rosenwald, is also an Affiliate of Manhattan. Manhattan is a development stage company and has no revenues to date. The agreement has conditions that stipulate that Manhattan has to raise certain funds before the Company receives the remaining license fee. There is no assurance that Manhattan can achieve this. If Manhattan is unable to raise additional funds, there is significant doubt it would be able to fulfill its remaining commitments to the Company. See also Notes 6 and 7 to the Financial Statements.

Business Strategy

NovaDel's strategy is to concentrate its product development activities primarily on those pharmaceuticals for which there already are significant prescription and OTC sales, where the use of NovaDel's innovative delivery system 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.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we will seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. NovaDel 's lack of working capital has impaired its ability to pursue its strategy. See "Management Discussion and Analysis."

Patented and Patent Pending Delivery Systems

NovaDel has certain patents and pending patent applications for its Lingual (Oral) Spray delivery system. FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA prior to marketability, and the amount of regulatory oversight required by the FDA will also depend on the specific type of drug product for which the delivery system is implemented. The following is a description of the oral dosage delivery system for which patent applications are either granted or pending:

Lingual (Oral) Spray. NovaDel's aerosol and pump spray formulations release the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. NovaDel believes that this delivery system offers certain advantages, including improving the safety profile of certain drugs by lowering the required dosage, improving dose reliability, and allowing medication to be taken without water. 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

NovaDel's proposed products described below 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 a NDA for its review and approval under Section 505(b)(1) or Section 505(b)(2) of the FDC Act. An NDA submitted under section 505(b)(2) of the FDC Act is generally less complex than an ordinary NDA. It is NovaDel's expectation that the majority of its products in development will require the filing of these shorter versions of an NDA because the products are known chemical entities, but NovaDel or its licensees will be making new claims as to therapeutic effects or lessened side effects, or both.

NovaDel estimates that development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five years for the ANDA process. Development of products requiring additional clinical studies under Section 505(b)(2) NDAs, may take four to seven years. There can be no assurance that NovaDel's determinations will prove to be accurate or that pre-marketing approval relating to its proposed products will be obtained on a timely basis, or at all. See "Government Regulation."

NovaDel's currently proposed products fall into the following therapeutic classes:

o Cardiovascular (Nitroglycerin)

NovaDel's Nitroglycerin product has been formulated and stability testing has been completed. A United States patent was issued in 1999. An IND was filed with FDA in early 2002 and clinical trials began in July 2002 and were completed in December 2002. NovaDel anticipates filing an NDA in the fourth quarter of 2003.

o Antihistamine (Loratadine) Lingual Spray

A loratadine lingual spray formulation has been developed and successfully undergone stability testing. An IND was filed in the fourth quarter of 2000 and a pharmacokinetic study was completed in the second quarter of 2001. A phase II clinical trial has been completed and the results are being evaluated. NovaDel is seeking a development partner to complete development of this product.

o Antihistamine (Clemastine) Lingual Spray

The formulation of clemastine lingual spray was revised, and an IND was filed. A pilot nasal challenge efficacy study was initiated in the second quarter of 2000. and 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, 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. NovaDel is seeking a partner to complete development of this product.

Marketing and Distribution

NovaDel intends, generally, to license products developed with its technology to other drug companies, or to market its products to pharmaceutical wholesalers, drug distributors, drugstore chains, hospitals, United States governmental agencies, health maintenance organizations and other drug companies. It is anticipated that promotion of the NovaDel 's 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. NovaDel will seek to position its proposed products as alternatives or as line extensions to brand-name products. NovaDel believes that to the extent that the NovaDel 's 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 substitute products after patent protection on existing products expire.

Inasmuch as NovaDel does not have the financial or other resources to undertake extensive marketing activities, NovaDel generally intends to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties.

NovaDel believes that such third-party arrangements will permit it to maximize the promotion and distribution of its products while minimizing NovaDel's direct marketing and distribution costs. Except for the agreement with Manhattan Pharmaceutical, NovaDel has not entered into any agreements or arrangements with respect to the marketing of its proposed products and there can be no assurance that it will do so in the future. See the discussion regarding Manhattan above and also see Notes 6 and 7 to the Financial Statements. There can be no assurance that NovaDel's proposed products can be successfully marketed.

Strategies relating to marketing of NovaDel's other proposed formulated products have not yet been determined; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. As a company, NovaDel has no experience in marketing or distribution of its proposed proprietary products, and NovaDel's ability to fund such marketing activities will require NovaDel to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

Manufacturing

NovaDel has determined to internalize the manufacturing of its proposed products. Presently, NovaDel has established a pilot manufacturing facility at its present location, which it believes is adequate for its needs in manufacturing our requirements for formulation development, stability testing and clinical supplies. It has also leased a new, larger facility which will have adequate space for its future foreseeable requirements for production manufacturing and warehouse space. This new space is presently being prepared for occupancy, which began in third quarter of 2003. The manufacture of NovaDel's pharmaceutical products will be subject to current Good Manufacturing Processes ("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 "Government Regulation" and "Raw Materials and Suppliers." There can be no assurance, however, that NovaDel will be successful in constructing and maintaining such a manufacturing and warehousing facility in compliance with cGMP. If it is unable to do so, it will become necessary for NovaDel to make

arrangements with a third party contract manufacturer to satisfy NovaDel's requirements. There can be no assurance that, if necessary, NovaDel will be able to do so, or be able to do so on commercially satisfactory terms. Failure of NovaDel to complete successfully the internalization of its manufacturing requirements, or to conclude an alternative contract manufacturing arrangement, could have an adverse effect on NovaDel's efforts to obtain regulatory approval for or to commercialize its products.

It is anticipated that NovaDel will arrange with third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of NovaDel's proposed products. It is NovaDel's present intent to seek to enter into similar manufacturing arrangements for other products to be developed by it in the future.

In addition, the raw materials necessary for the manufacture of NovaDel's products will, in all likelihood, be purchased by NovaDel from suppliers in the United States, Europe and Japan and delivered to its manufacturing facility by such suppliers.

Accordingly, NovaDel 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 to NovaDel of the manufactured product). 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), the operating results of NovaDel will be affected by fluctuations in foreign currency exchange rates.

Raw Materials and Suppliers

NovaDel believes that the active ingredients used in the manufacture of its proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe and Japan. 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 NovaDel's lingual spray products may be only available from sole source suppliers. Although NovaDel believes that it will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of its products, there can be no assurance that NovaDel will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. The 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 the ability to manufacture formulated products.

Development and regulatory approval of NovaDel's pharmaceutical products are dependent upon NovaDel's 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, NovaDel will seek to locate alternative FDA approved suppliers.

Government Regulation

The development, manufacture and commercialization of pharmaceutical products are generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations, pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures.

Under the Food, Drug and Cosmetic (FDC) Act, a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA.

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 a 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 ten (10) to twenty four (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 Act this time frame may be significantly shorter. NovaDel believes that most products developed in lingual spray delivery systems (dosage forms) usually will require submission of an NDA under Section 505(b)(2).

NovaDel estimates 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 NDAs 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. There can be no assurance that NovaDel's determinations will prove to be accurate or that pre-marketing approval relating to its proposed products will be obtained on a timely basis, or 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 NovaDel's 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 NovaDel intends to enter are characterized by intense competition. NovaDel will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those NovaDel intends 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 NovaDel's proposed products. NovaDel expects 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 NovaDel has targeted for development are intensely competitive, involving numerous competitors and products. NovaDel will seek to enhance our competitive position by focusing our efforts on our novel dosage forms.

Patents and Protection of Proprietary Information

NovaDel has applied for United States and foreign patent protection for the buccal spray delivery systems which are the primary focus of its development activities as well as for NovaDel's delayed contact allergy topical formulations. Four United States patents have been issued and other applications are pending. There can be no assurance, however, that any additional patent applications will be granted, or, if granted, will provide adequate protection to NovaDel. NovaDel also intends 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 NovaDel believes that its technology has been developed independently and does not infringe on the patents of others, there can be no assurance that the technology does not and will not infringe on the patents of others. In the event of infringement, NovaDel could, under certain circumstances, be required to modify its infringing product or process or obtain a license. There can be no assurance that NovaDel would be able to do either of those things in a timely manner or at all, and failure to do so could have a material adverse effect on NovaDel and its business. In addition, there can be no assurance that NovaDel will have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend itself against such actions brought by others. If any of the products developed by NovaDel infringe upon the patent or proprietary rights of others, NovaDel could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on NovaDel.

NovaDel also relies on confidentiality and nondisclosure arrangements with its licensees and potential development candidates. There can be no assurance that other companies will not acquire information which NovaDel considers to be proprietary. Moreover, there can be no assurance that other companies will not independently develop know-how comparable to or superior to that of NovaDel.

Buccal Nonpolar Sprays. On April 12, 1996 NovaDel filed an application with the United States Patent and Trademark Office ("USPTO") with claims directed to a 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 compositions, but rejected the claims directed to the capsules. In November 1998 NovaDel 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 issued to NovaDel with claims directed to the above-described buccal non-polar spray compositions and methods.

On February 21, 1997, NovaDel filed an application under the Patent Cooperation Treaty ("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 NovaDel disagrees, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where NovaDel enters the national phase.

With respect to the above PCT application, in October and November 1998 NovaDel 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 NovaDel with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs to those in the corresponding

issued U.S. patent. In Canada, a request for examination was filed with the Canadian Patent Office on February 7, 2002. An office action has not yet been received from the Canadian Patent Office.

Buccal Polar Sprays. On April 12, 1996, NovaDel 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. NovaDel 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 issued to NovaDel with claims directed to the above-described methods of administering the drugs

On February 21, 1997 NovaDel 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 lacked novelty and/or lacked an inventive step. This opinion, with which NovaDel disagrees, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where NovaDel enters the national phase.

With respect to the above PCT application, in October and November 1998 NovaDel entered the national phase in Canada and Europe, respectively. In Canada, a request for Examination was filed on February 7, 2002. An office action has not yet been received from the Canadian Patent Office. In Europe, claims directed to using the propellant free buccal polar spray composition to manufacture a medicament containing the various classes of drugs is currently being

prosecuted.

Buccal Nonpolar Spray for Nitroglycerin. On April 12,1996 NovaDel 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 a U.S.Patent No. 5,869,082 to NovaDel for said nitroglycerin buccal spray.

On February 21, 1997, NovaDel 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 NovaDel disagrees, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where NovaDel enters the national phase.

In October 1998, NovaDel entered the national phase in Canada. A request for examination was filed on February 7, 2002. An office action has not been received from the Canadian Patent Office.

In November 1998, NovaDel entered the national phase in Europe. A European patent was granted on April 16, 2003 with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant.

Buccal Polar/Nonpolar Sprays or Capsules. On October 1, 1997 NovaDel filed a PCT application designating a large number of countries including the United States, directed to the above-described subject matter. The application included claims directed to a buccal spray composition containing either a polar solvent with certain classes of drugs, as well as specific drugs in those classes or a non-polar solvent and a propellant with certain classes of drugs, as well as specific drugs in those classes; buccal spray composition containing a non-polar solvent, a flavoring agent, and certain classes of drugs; and

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 NovaDel disagrees, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where NovaDel enters the national phase.

On March 29, 2000, NovaDel 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, a divisional application was filed claiming priority to the CIP.

The 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.

Based on the above-identified PCT application, NovaDel entered the national phase in Canada on March 29, 2000. A request for examination was filed on August 29, 2002. An office action has not been received from the Canadian Patent Office.

Based on the above-identified PCT application, NovaDel also entered the national phase in Japan on April 3, 2000. A request for examination has not yet been filed. A request for examination must be filed before October 1, 2004 to pursue patent protection in Japan.

Based on the above-identified PCT application, NovaDel 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 transmucossal administration. Four divisional applications based on this application have also been filed in Europe. The first divisional 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 transmucossal administration. The second divisional 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 divisional application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant, and an alkaloid or analgesic. The fourth divisional 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.

Antihistamine Syrup and Ointment. On November 10, 1997 NovaDel 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 issued to for the above-described method.

On November 9, 1998 NovaDel filed the above-identified application with the Canadian Patent Office and on October 29, 2002 a request for examination was filed. An office action has not been received from the Canadian Patent Office.

General Comment with Respect to entering the national phase for each of the foregoing PCT Applications. In addition to its patents and patent applications in the United States, NovaDel is interested in entering the national phase and

obtaining patent protection in Europe and Canada. At the present time, it is not possible accurately to predict the expenses involved in pursuing the foregoing applications in Canada and Europe. For example, NovaDel anticipates 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.

Product Liability

NovaDel may be exposed to potential product liability claims by consumers. NovaDel does not presently maintain product liability insurance coverage. Although NovaDel will seek to obtain product liability insurance prior to the commercialization of any products, there can be no assurance that NovaDel will obtain such insurance or, if obtained, that any such insurance will be sufficient to cover all possible liabilities. In the event of a successful suit against NovaDel, insufficiency of insurance coverage could have a material adverse effect on NovaDel. 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. Failure to satisfy such insurance requirements could impede the ability of NovaDel or its distributors to achieve broad retail distribution of its proposed products, which would have a material adverse effect upon the business and financial condition of NovaDel.

Employees

The Company currently has twenty (20) full-time employees, five (5) of whom are executive officers of the Company, ten (10) of whom are laboratory or support personnel and five (5) of whom are engaged in administrative functions. The success of the Company will be dependent in part, upon its ability to hire and retain additional qualified sales, manufacturing and distribution personnel, however, there can be no assurance that the Company will be able to hire or retain such necessary personnel.

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 have a history of losses and our auditors have qualified their audit opinion with regard to our ability to continue as a going concern

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We had an accumulated deficit at July 31, 2003 of approximately $15,628,000. We incurred operating losses in all of the last eight fiscal years ended July 31 including a net loss of approximately $5,815,000 for the year ended July 31, 2003. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued development, 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. Because our rate of expenses is high, and our very limited resources, our auditors have qualified their audit opinion with regard to our ability to continue as a going concern.

We will require significant capital requirements for product development and commercialization

We have significant capital requirements necessary to fund planned expenditures in connection with the research, development, testing and approval of our proposed products. 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), that the proceeds of our recent private placement and projected cash flow from operations will be sufficient to satisfy our contemplated cash requirements for the remainder of the calendar year 2003. Due to our small revenue base, low level of working capital and inability to increase the number of development agreements with pharmaceutical companies, we have been unable to aggressively pursue 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 there can be no assurance that additional financing will be available to us on acceptable terms, if at all. Unless we raise additional financing or significantly reduce our expenses, we will not have sufficient funds and we will not be to complete development and commercialization of our proposed products or continue operating. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Our business and revenue is dependent on the successful development of our products

Revenue received from our product development 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, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. There can be no assurance that we will be able to raise additional financing, increase revenues significantly, or achieve profitable operations.

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 licensees, will not begin until 2004 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. There can be no assurance that any of the proposed proprietary products will prove to be commercially viable, or if viable, that they will reach the marketplace on the timetables desired by us. The failure or the delay of these products to achieve commercial viability would have a material adverse effect on us. See "Business - Proposed Products" and " - Government Regulation."

We have not completed product development

The development of our proposed products has not been completed 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 2004 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. There can be no assurance that any of our proposed products will be successfully developed, be developed on a timely basis or be commercially accepted once developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on us.

We do not have direct consumer marketing experience

We have no experience in marketing or distribution at the consumer level of our proposed proprietary 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. We have not entered into any significant agreements or arrangements with respect to the marketing of our proposed products, and there can be no assurance that we will do so in the future or that any such products can be successfully marketed. Our strategy to rely on third party marketing arrangements could adversely affect our profit margins. See "Business - Marketing and Distribution."

We must comply with good manufacturing practices

The manufacture of our pharmaceutical products will be subject to current Good Manufacturing Practices ("cGMP") prescribed by the FDA, pre-approval inspections by the FDA or foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. There can be no assurance that we or any third party manufacturer will be able to comply with cGMP or satisfy pre- or post-approval inspections 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 us. See "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 products, there can be no assurance that we will 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 the nitroglycerin lingual spray product. 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 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 could result in manufacturing delays. See "- Business- Raw Materials and Suppliers."

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. There can be no assurance that we will have the ability to compete successfully. See "Business - Competition."

The absence of product liability insurance coverage may affect our business

We may be exposed to potential product liability claims by consumers. We presently maintain no product liability insurance coverage. Although we will seek to obtain product liability insurance before the commercialization of any proprietary products, there can be no assurance that we will be able to obtain such insurance or, if obtained, that any such insurance will be sufficient to cover all possible liabilities to which we may be exposed. In the event of a successful suit against us, insufficiency of insurance coverage could have a material adverse effect on us. 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. 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. See "Business - Product Liability."

Extensive government regulation may affect our business

The development, manufacture and commercialization of pharmaceutical products are generally subject

to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations, pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the "FDC Act", a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA. 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 ("NDA"), including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. 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 ingredient 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 products developed in spray dosage form will require 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. There can be no assurance that our determinations will prove to be accurate or that pre-marketing approval relating to our proposed products will be obtained on a timely basis, or 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.

We may not be able to protect and enforce our intellectual property rights.

Our patents, pending patents and other intellectual property rights in the United States and in selected other countries may not be allowed or competitors may challenge the validity or scope of these rights. In addition, our intellectual property rights may not provide us with a significant competitive advantage. In addition, competitors may design around our proprietary technology or develop competing technologies. Effective patent, trademark, service mark, copyright and trade secret protection may not be available in every country in which we may offer our product.

We rely on a combination of patents, trademarks, trade secrets, confidentiality agreements and licensing arrangements to establish and protect our proprietary technology. Employees, consultants and customers have access to our proprietary and confidential information. Any misuse or misappropriation of this intellectual property could have an adverse impact on our business. We take

steps to control access to, and the distribution of, our proprietary information. We cannot guarantee, however, that such safeguards will protect our intellectual property and other valuable competitive information. If we fail to successfully enforce our intellectual property rights, our competitive position will suffer.

Because our success depends on our proprietary technology, if third parties infringe our intellectual property, we may be forced to expend significant resources enforcing our rights or suffer competitive injury. We may not be able to detect infringement and may lose our competitive position in the market before we do so.

Although there are no pending lawsuits regarding our technology or notices that we are infringing upon intellectual property rights of others, litigation or infringement claims may occur in the future. Such litigation or claims could result in substantial costs, and diversion of resources and could have a material adverse effect on our business, financial condition, and results of operations.

We are dependent on existing management

Our success is substantially dependent on the efforts and abilities of our President and Chief Executive Officer, Gary A. Shangold, MD, our founder and Chief Scientific Officer, Harry A. Dugger, III, Ph.D., our Chairman, John Klein, our Chief Financial Officer, Donald Deitman, our Vice President - Formulation Development, Mohammed Abd El-Shafy, Ph.D., and our Vice President-New Business and Product Development, Barry Cohen. Mr. Klein is not required to devote full time to us. 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.

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) approximately 55 % of our common stock. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board of Directors and other matters submitted to our stockholders for approval. These arrangements may discourage or prevent any proposed takeover of NovaDel, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market prices. Such stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

There is a potential adverse effect if we redeem our publicly traded warrants

The 680,000 warrants issued in connection with our initial public offering may be redeemed by us, at a redemption price of $.10 per warrant, upon not less then thirty days prior written notice provided the last sale price of our common stock on the NASD OTC Bulletin Board, Nasdaq (or another national securities exchange) for twenty consecutive trading days ending within three days of the notice of redemption, equals or exceeds 200% of the current warrant exercise price ($5.80), subject to adjustment. Redemption of the warrants could force the holders thereof to exercise the warrants and pay the exercise price at a time

when it may be disadvantageous for the holders to do so, to sell the warrants at the then current market price when they might otherwise wish to hold the warrants, or to accept the redemption price, which is likely to be substantially less than the market value of the warrants at the time of redemption. The warrants expire on November 18, 2003.

The limited prior public market and trading market may cause possible volatility in our stock price

There has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. The OTC Bulletin Board is an unorganized, inter-dealer, over-the-counter market which provides significantly less liquidity than the Nasdaq Stock market, and quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers as are those for the Nasdaq Stock Market. In addition, the stock market in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices

of many smaller companies. The trading price of our common stock is expected to be subject to significant fluctuations in response to variations in quarterly operating results, changes in analysts' earnings estimates, announcements of innovations by us or our competitors, general conditions in the industry in which we operate and other factors. These fluctuation, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

Penny stock regulations may impose certain restrictions on marketability of our securities

The Securities and Exchange Commission (the "Commission") has adopted regulations which generally define a "penny stock" to be any equity security that has a market price (as defined) of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by these 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. 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.

Shareholders should be aware that, according to the Securities and Exchange 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 a few 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. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our common stock.

Additional authorized shares of common stock and preferred stock available for issuance may adversely affect the market

We are authorized to issue 50,000,000 shares of our common stock. As of July 31, 2003 there were 17,972,760 shares of our common stock issued and outstanding. However, the total number of shares of common stock issued and outstanding does not include the exercise of options or warrants. We have reserved up to 15,325,755 shares of our common stock for issuance upon exercise of stock options and warrants. Of the reserved shares, a total of 2,800,000 shares were reserved among NovaDel's 1992, 1997 and 1998 Stock Option Plans, of which options to purchase an aggregate of 300,000, 450,000 and 892,500 shares are issued and outstanding under the respective Plans. (Collectively, a total of 455,000 options issued among the three Plans have been exercised.) Another 3,800,000 shares are reserved for issuance and available for non-plan options granted pursuant to the terms of certain employment agreements. A significant number of such options and warrants contain provisions for cashless exercise.

Exercise of the outstanding convertible securities, will reduce the percentage of common stock held by the public stockholders. Further, the terms on which we could obtain additional capital during the life of the convertible securities may be adversely affected, and it should be expected that the holders of the convertible 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 convertible securities. As a result, any issuance of additional shares of common stock may cause our current shareholders 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 shareholder 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 shareholder 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 could have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market

Of the 17,972,760 shares of common stock outstanding as of July 31, 2003, 14,472,415 shares may be available for public sale by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act, subject to certain limitations. In general, under Rule 144, a person (or persons 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 a person who is not an affiliate of NovaDel and who has satisfied a two-year holding period.

We have reserved up to 15,325,755 shares of common stock for issuance upon exercise of various stock options and warrants, of which 1,600,000 shares were registered under a Registration Statement on Form S-8 and 4,257,242 shares under a Registration Statement on Form SB-2 under the Act. Any substantial sale of common stock pursuant to Rule 144 or those registration statements may have an 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 determine that we will pay dividends to the holders of our common stock, there is no assurance or guarantee that such dividends will be paid on a timely basis.

ITEM 2. PROPERTIES

Our executive offices are located at 25 Minneakoning Road,, Flemington, New Jersey. The facility, constituting approximately 31,800 square feet, is occupied under a ten-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. No rent or taxes were payable on this space during fiscal 2003. 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 2003, the Company paid rent of approximately $92,000, including real estate taxes, for that space.

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 the fiscal year covered by this report, no matters were submitted to a vote of security holders, though the solicitation of proxies or otherwise.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED

STOCKHOLDER MATTERS

(a) Market Information. Since the November 1997 closing of the public offering, the Company's Common Stock has traded in the over-the-counter market on the National Association of Securities Dealers, Inc. OTC Bulletin Board System ("OTC.BB"). Since October 1, 2002, the symbol has been "NVDL". Before that, the Common Stock traded under the symbol "FLEM". The following table sets

forth the range of high and low closing bid quotations of the Common Stock as reported by the OTCBB for each fiscal quarter for the past three fiscal years. High and low bid quotations represent prices between dealers without adjustment for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

	Bid Prices	
	High	Low
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
FISCAL 2002		
First Quarter (August 1, 2001 through October 31, 2001)	.60	.43
Second Quarter (November 1, 2001 through January 31, 2002)	2.30	.63
Third Quarter (February 1, 2002 through April 30, 2002)	3.79	2.40
Fourth Quarter (May 1, 2002 through July 31, 2002)	3.62	1.65
FISCAL 2001		
First Quarter (August 1, 2000 through October 25, 2000)	2.125	.969

Second Quarter (November 1, 2000 through January 31, 2001)	1.562	.438
Third Quarter (February 1, 2001 through April 30, 2001)	1.094	.550
Fourth Quarter (May 1, 2001 through July 31, 2001)	.950	.510

The closing bid price of the Company's Common Stock as reported by the OTCBB was $2.01 on October 27, 2003.

(b) Holders. As of October 27, 2003 there were approximately 74 record holders of the Company's 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 the 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 the Common Stock in the foreseeable future. Moreover, there can be no assurance that dividends can or will ever be paid.

(d) Recent Sales of Unregistered Securities.

In April and May 2003, we sold Units (consisting of common stock and warrants) to accredited investors. Investors were issued one warrant for each four shares purchased. The warrants are exercisable for five years, at an exercise price of $2.00 per share. The securities were sold through Paramount Capital, Inc., a NASD broker- dealer. The gross proceeds of the private offering were approximately $4.8 million. For its services as placement agent, we paid Paramount a 7.5% commission fee of the aggregate amount raised (approximately $360,000) and also issued to Paramount warrants to purchase 160,017 shares of common stock at an exercise price of $1.65 and 40,004 shares of common stock at an exercise price of $2.00. In connection with the offering, we agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the shares of common stock and the shares underlying the warrants (as well as the shares underlying Paramount's warrants). We also agreed that if, at any time following the closing of the offering and continuing for a period of two (2) years thereafter, we offer shares of our common stock for sale in a capital raising transaction, we will permit the investors to purchase such number of shares of common stock to maintain their pro rata ownership percentages of NovaDel. We also agreed that if, at any time following the closing of the offering for a period of one year, we sold shares of common stock in a capital raising transaction (of at least $1 million) at a per share price less than $1.50, we will issue to the investors additional shares of common stock (so that they would receive their original shares at such lower price).

During the fourth quarter of fiscal 2003, a total of 210,577 shares of the Company's Common Stock were issued in connection with the cashless exercise of 445,000 options.

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

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, 2003 of approximately $15,628,000. 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's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company incurred losses during the fiscal years ended July 31, 2003 (fiscal 2003) and 2002 (fiscal 2002) and had an accumulated deficit at July 31, 2003 of approximately $15,628,000.

The Company's continued existence is dependent upon its ability to achieve profitable operations or obtain additional financing. The Company is currently seeking collaborative arrangements with pharmaceutical companies for joint development of delivery systems and the successful marketing of these delivery systems. In order to pursue this strategy, the Company will be required to obtain financing and/or consummate a strategic alliance with a well-funded business partner in the near future. In view of

the Company's very limited resources, its anticipated expenses (resulting in significant operating losses) and the competitive environment in which the Company operates, there can be no assurance that the Company's operations will be sustained for the duration of its next fiscal year.

Results of Operations

Fiscal Year 2003 Compared to Fiscal Year 2002

Consulting revenues for fiscal 2003 decreased approximately $337,000 or 99% to $2,000 from $339,000 for fiscal 2002. This revenue decrease for fiscal 2003 was primarily attributable to a decrease in project management of clinical studies for clients.

Consulting expenses increased approximately $86,000 or 9% to $1,048,000 from $962,000 for fiscal 2002. This increase was due to increased payroll and inside laboratory expenses. Selling, general and administrative expenses increased approximately $1,135,000 or 30% to $4,902,000 from $3,767,000 for fiscal 2002. This increase was due, primarily, to the increase in payroll expenses.

Total costs and expenses for fiscal 2003 increased approximately $1,221,000 or 26% to approximately $5,950,000 from approximately $4,729,000 for fiscal 2002.

This increase includes approximately: $880,000 in payroll expense primarily due to additional employees; $476,000 in deferred compensation expense attributable to options issued to an employee with an exercise price significantly lower than the current share price; $307,000 in legal & professional fees; $104,000 in laboratory testing and clinical studies costs; $68,000 in insurance expense due to additional employees and general premium increases; $26,000 in trade show and conference expenses; $19,000 in office expense due to additional employees; $17,000 in laboratory expenses due to additional lab employees; $16,000 in travel expenses; $14,000 in outside services; and, $12,000 in automobile

expenses.

Decreases in costs and expenses for the 2003 Period, as compared to the 2002 Period, includes approximately: $554,000 in outside consultant fees due primarily to a reduction in the options issued to consultants; $131,000 in bad debt expense; and, $20,000 in employee recruiting and relocation. A buy-out of a consultant's contract, during the 2002 Period, without a corresponding expense during the 2003 Period, resulted in an approximate $32,000 decrease in expenses.

Deferred income tax benefit for fiscal 2003 was approximately $84,000 compared to approximately $88,000 for fiscal 2002. These benefits resulted from the sale of the Company's New Jersey net operating losses.

The resulting net loss for fiscal 2003 was $5,815,000 compared to a net loss of $4,290,000 for fiscal 2002.

Liquidity and Capital Resources

From its inception, the Company's principal sources of capital have been provided by 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, 2003 we had working capital of approximately $2,799,000 as compared to working capital of $3,095,000 at July 31, 2002 representing a net decrease in working capital of approximately $296,000. During fiscal 2003, we successfully closed an offering of our securities ("Private Placement"). The Private Placement provided for the sale of

approximately 3,200,000 shares of common stock, par value $.001 per share. We received proceeds, net of offering costs, of approximately $4,336,000.

Net cash used in operating activities was approximately $4,320,000 for fiscal 2003 compared to net cash used in operating activities of approximately $1,871,000 for fiscal 2002. Net cash used in operating activities for fiscal 2003 was primarily attributable to the net loss of $5,815,000.

We believe that our current cash levels together with revenues from operations, will be sufficient to satisfy our cash requirements for calendar year 2003. However, beyond this point there is substantial doubt about our ability to continue operations without obtaining additional financing and/or consummating 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 our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. These uncertainties raise substantial doubt as to our ability to continue as a going concern. Our auditors have qualified their audit opinion with regard to our ability to continue as a going concern.

Critical Accounting Policies

Use of Estimates - The accompanying financial statements have been prepared in conformity with accounting principle generally accepted in the United States. When more than one accounting principle, or method of its application, is generally accepted, management selects the principle or method that is appropriate in the Company's specific circumstances. Application of the accounting principles requires the Company's management to make estimates about the future resolution of existing uncertainties and that affect the reported

amounts of assets, liabilities, revenues, expense 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. An Allowance for Doubtful Accounts is created for each invoice remaining unpaid after 90 days from the invoice date.

Stock - Based Compensation - The Company uses the intrinsic value method prescribed by APB Opinion No. 25 to measure compensation expense. If the fair value method had been used to measure compensation expense as prescribed by SFAS No. 123, net loss would have increased to $6,301,000 for fiscal 2003.

Capital Expenditures - The Company anticipates a twelve (12) to eighteen (18) months to complete the remaining build-out of its recently occupied leased facilities for laboratory and manufacturing purposes. Costs of the build-out and necessary equipment are estimated to be up to $3,500,000

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

We do not believe that inflation has had a material effect on our results of operations during the past three fiscal years. There can be no assurance that our business will not be affected by inflation in the future.

New Accounting Pronouncements

See Note 1 to the Financial Statements for a discussion of New Accounting Pronouncements affecting the Company.

ITEM 7. FINANCIAL STATEMENTS

The response to this item is 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

As of July 31, 2003, our Chief Executive Officer and Chief Financial Officer performed an evaluation of the effectiveness of the Company's disclosure controls and procedures (as defined in SEC Rule 13a-15(e)), which have been designed to ensure that material information related to the Company is made known to them and timely disclosed. The Company's management, including the CEO

and CFO, does not expect that the Company's disclosure controls or internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Notwithstanding the foregoing, however, based upon their evaluations, our CEO and CFO concluded that the Company's disclosure controls are effective to provide a reasonable level of assurance that material information relating to the Company is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes in the Company's internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The names and ages of the Directors and Executive Officers of the Company 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 and serve at the Board's pleasure.

Name	Age	Position with the Company	Principal Occupa
Gary A. Shangold, M.D.	49	President, Chief Executive Officer and Director	President and Chief E Officer of the Co
Harry A. Dugger, III, Ph.D.	67	Chief Scientific Officer	Chief Scientific Offic Company
John H. Klein	57	Chairman	Consultant
Robert F. Schaul, Esq.	64	Secretary and Director	Attorney
Donald J. Deitman	60	Chief Financial Officer	Chief Financial Offic Company
Mohammed Abd El-Shafy	50	Vice President, Formulation Development	Vice President of For Development for the
William F. Hamilton, Ph.D.	64	Director	University Profe
Lawrence J. Kessel, M.D., FACP	49	Director	Physician

Mark H. Rachesky, M.D.	44	Director	Investment Bank
Charles Nemeroff, M.D., Ph.D.	54	Director	University Profe
Barry Cohen	40	Vice President - New Business and Product Development	Vice President - New and Product Developme Company

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 MS in Chemistry from the University of Michigan in 1960 and received a Ph.D. in Chemistry from the University of Michigan in 1962.

John H. Klein, Chairman of the Board. Mr. Klein joined NovaDel in February 2002 as a consultant and as Chairman of its Board of Directors. From April 1996 to the present Mr. Klein has been affiliated with a number of enterprises, including True North Capital (Chairman/ Managing Director), Kindred Healthcare (Director), US Interactive, Inc. (Director), America's Plan (Director and Chairman), Coleman Co., Inc. (Director), Sunbeam Corp. (Director), Bi- Logix, Inc. (Director), Strategic Business and Technology Solutions, LLC (Chairman), Cybear (Director and Chairman) and Image Vision (Director and Vice Chairman). From 1996 to 1998, Mr. Klein was Chairman and CEO of Mim Corp. From 1989 to 1996, he was President, CEO and Director of Zenith Laboratories, Inc., which in 1995 merged into IVAX, Inc., of which Mr. Klein was an Executive Officer and President of its IVAX North American Multi-Source Pharmaceutical Group. Mr. Klein holds BS and MBA degrees from Roosevelt University, Chicago, Illinois.

Donald Deitman, 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. From 1975 to 1982, he was manager of materials and systems for the Walworth Company operations located in Linden and Elizabeth, NJ and from 1966 to 1975, he was employed by Ortho Pharmaceuticals, Inc. and Ortho Diagnostics, Inc.

Mr. Deitman received a BS in Accounting from Rutgers University in 1972.

Robert F. Schaul, Esq., Secretary and Director. Mr. Schaul has been a Director of NovaDel since November 1991 and was Vice President, Secretary and General Counsel of NovaDel from November 1991 to February 1995. He has 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. From 1989 to 1991, Mr. Schaul was a partner with the law firm of Glynn, Byrnes and Schaul, and for twenty years prior thereto was an attorney and partner with the law firm Kerby, Cooper, English, Schaul & Garvin, specializing in business law and business related litigation. Mr. Schaul received a BA from New York University in 1961 and a JD from Harvard University in 1964.

William F. Hamilton, Ph.D., Director. Dr. Hamilton was elected to the 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 the following publicly-held companies: Neose Technologies, Inc., a company developing a drug manufacturing process and proprietary drugs, and Digital Lightwave, Inc., a manufacturer of telecommunications test equipment. 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 and Compensation Committee.

Lawrence Jay Kessel, MD, FACP , Director. Dr. Kessel was elected to the Board in March 2003. He is President of Lawrence J. Kessel, MD & Associates, PC, Dr Kessel is president of a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He graduated Magna Cum Laude

with a B.S. degree from the University of Pittsburgh as an honors major in Biology and subsequently graduated with an MD 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 to Cypress Biosciences, Inc. of San Diego, California, NovaDel Pharma Inc, of Flemington, New Jersey, Keryx Biopharmaceuticals, of New York, New York, and Dor BioPharma, Inc. of Lake Forest, Illinois. He previously served on the Board of Genta, Inc.

Mohammed Abd El-Shafy, Ph.D., Vice President-Formulation Development. Dr. El-Shafy has been an employee of NovaDel since May of 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, and before that held several executive marketing and business development positions at Novartis Consumer Health. Mr. Cohen holds a BBA in Marketing from Hofstra University and an MBA in Marketing from Pace University.

Mark H. Rachesky, M.D., Director. Dr. Rachesky joined the 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 major in Molecular Aspects of Cancer.

Charles Nemeroff, M.D., Ph.D. Dr. Nemeroff joined the Board in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at 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 Neuropsychopharacology. 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 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.

Code of Ethics

The Company's Board of Directors has been actively considering adoption of a Code of Ethics to be applicable to its Chief Executive Officer and senior financial executives. The Code of Ethics will 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 anticipates it will adopt the Code of Ethics before the end of the calendar year. Following adoption. a copy of the Code of Ethics will be provided to any person without charge upon written request to the Secretary of the Company at its executive offices, 25 Minneakoning Road, Flemington, N.J.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Exchange Act requires officers, directors and persons who own more than ten (10) percent 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 ten (10) percent of the outstanding shares of a class of Section 12-registered equity securities ("Reporting Persons") are also required to

furnish copies of any such reports filed pursuant to Section 16(a) of the Exchange Act with the Company. Based solely on a review of the copies of such forms furnished to the Company, the Company believes that from August 1, 2002 to July 31, 2003 all Section 16(a) filing requirements applicable to its Reporting Persons were complied with.

ITEM 10. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following table sets forth a summary for the fiscal years ended July 31, 2003, 2002 and 2001, respectively, of the cash and non-cash compensation awarded, paid or accrued by the Company to the Company's Chief Executive Officer ("CEO") and its four most highly compensated officers other than the CEO who served in such capacities at the end of fiscal 2003 (collectively, the "Named Executive Officers"). There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2001, 2002 and 2003 to the Named Executive Officers, except as set forth below:

SUMMARY COMPENSATION TABLE

		ANNUAL COMPENSATION			LONG-TERM COM	
					AWARDS	
NAME AND PRINCIPAL POSITION	FISCAL YEAR	SALARY ($)	BONUS ($)	OTHER ANNUAL COMPENSATION ($)	RESTRICTED STOCK AWARD(S) ($)	SECURI UNDER- OPTIO SAR (#
Gary A. Shangold, M.D. President and CEO	2003	210,900	200,000	0	0	1,000
Harry A. Dugger, III, Ph.D. Chief Scientific Officer, formerly President and CEO	2003	246,900	0	0	0	275,
	2002	347,000	0	0	0	0
	2001	182,974	0	0	0	0
John H. Klein Chairman	2003	300,000	0	0	0	0
	2002	150,000	0	0	0	1,000
Donald Deitman Chief Financial Officer	2003	124,200	0	0	0	0

	2002	104,400	0	0	0	0
	2001	70,800	0	0	0	0
Robert C. Galler Vice President Corporate Development	2003	186,900	0	0	0	350,
	2002	143,600	0	0	0	700,
Mohammed abd Al-Shafy, Ph.D., Vice President - Formulation Development	2003	144,000	0	0	0	100,

(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 2003:

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.	1,000,000	54 %	
Harry A Dugger III, Ph.D	275,000	15 %	
John H. Klein	0	N/A	
Donald J. Deitman	0	N/A	
Robert Galler	350,000	19 %	
Mohammed Abd El-Shafy, Ph.D.	50,000	3 %	
Barry Cohen	75,000	4 %	

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 2003 and the number and value of unexercised options held as of the end of fiscal 2003.

NAME OF EXECUTIVE OFFICER	NUMBER OF SHARES ACQUIRED ON EXERCISE	VALUE REALIZED ($)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR END; (EXERCISABLE/ UNEXERCISABLE)
Harry A. Dugger, III, Ph.D.	0	-	920,000/0
John H. Klein	0	-	333,333 / 666,667
Gary A. Shangold, M.D.	0	-	0 / 1,000,000
Donald Deitman	0	-	-
Mohammed Abd El-Shafy, Ph.D.	0	-	150,000/50,000
Robert Galler	0	-	1,050,000/0
Barry Cohen	0	-	0/75,000

Employment Agreements and Change in Control Arrangements

Gary A. Shangold, M.D.. In December 2002, Dr. Shangold entered into a three-year employment agreement with NovaDel pursuant to which he agreed to serve as its 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) invested in, or earned by, NovaDel during his term. We paid Dr. Shangold a contractual bonus of $200,000 during the fourth quarter. The investment bonus shall be reduced by certain proceeds received by Dr. Shangold from his former employer. 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, Dr. Dugger entered into a new three-year employment agreement 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%). Except for the increase in base salary, there was no material difference between the new employment agreement and that previously in effect.

John Klein. In February 2002, Mr. Klein entered into a one-year consulting agreement (which was renewed in February 2003 for an additional one year) at a base compensation of $300,000, plus certain fringe benefits of approximately $72,000 per year. Pursuant to the agreement, he was granted 1,000,000 non-plan options at $2.40 per share. See "Certain relationships and related transactions." Mr. Klein is also entitled to certain bonuses, in the form of stock, stock options or other rights or property, as determined by the Board. In addition, Mr. Klein is entitled to receive certain success fees (based upon a percentage of net revenues) upon completion of certain types of corporate transactions (i.e., strategic partnerships, licensing arrangements and the like) which are introduced to NovaDel by Mr. Klein. The percentage of net revenue (which is between 4% - 10%) depends upon the share of profits that NovaDel is entitled to in such transactions.

Donald Deitman. In February 2002, effective January 1, 2002, Mr. Deitman entered into a three year employment agreement 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%). All other provisions of the agreement are the same as those in effect for our other executives.

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-Formulation 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 addition, he was granted 150,000 non-plan options at $3.02 per share. Subsequently, in March 2003, Dr. El-Shafy was granted 50,000 options under the 1998 Option Plan at an exercise price of $1.51.

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.

Robert C. Galler. In August 2003, Mr. Galler agreed to change from an employee of the Company as our Vice President - Corporate Development to a consulting arrangement. At that time, his additional options to purchase 350,000 shares of our common stock at an exercise price of $.75 per share vested. In August 2003, he entered into a consulting agreement with the Company at a base compensation of $180,000 per year and the vesting of additional options. The consulting agreement terminates in February 2005.

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 (other than John Klein) provides for certain fringe benefits, such as inclusion in pension, profit sharing, stock option, savings, hospitalization and other benefit plans at such times as NovaDel shall adopt them.

Stock Option Plans

NovaDel has three stock option plans, adopted in 1992, 1997 and 1998, respectively (collectively referred to as the "Plans"). The 1992 and 1997 Plans

provides 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 1,800,000 shares of common stock, for a total of 2,800,000 shares. The 1997 Stock Option

Plan is administered by William Hamilton and Lawrence Kessel 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 employees and officers of the Company are eligible to participate in the Plans.

At July 31, 2003, 300,000, 450,000 and 892,500 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 $.63 and $2.69 per share.

The Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of 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 the 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 the outstanding common stock of NovaDel). Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only by an employee while employed by NovaDel 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 NovaDel, nor do the Plans interfere in any way with the employee's right or NovaDel's right to terminate the employee's employment at any time.

Non-Plan Options

As of July 31, 2003, we had 4,550,000 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 $2.40 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 $151 per share; 100,000 options exercisable at $2.15 per share; 250,000 options exercisable at $3.18 per share; and 150,000 options exercisable at $3.02 per share.

Compensation of Directors

The Directors of the Company 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, Directors of the Company 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 for serving or $5,000 for chairing a committee of the Board. Such Directors also are awarded 100,000 Non-Plan Options upon their election to the Board, 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 for each year of service on the Board thereafter, beginning on the first anniversary of their election; 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 Mr. William Hamilton and Dr. Lawrence 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 Komreich under the 1998 Plan. All of these options have an exercise price of $1.51; the options issued to Messrs. Schaul and Kornreich 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 June, 2003, we issued 100,000 Non-Plan Options to Dr. Mark H. 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.

There were no other arrangements pursuant to which any Director was compensated during fiscal 2003 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 October 15, 2003 with respect to the beneficial ownership of the outstanding shares of our common stock (17,972,760 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.	2,104,003(2)
Common Stock	Gary A. Shangold, M.D.	333,333(3)
Common Stock	John Klein	333,333(4)

Common Stock	Robert Galler	1.050,000(5)
Common Stock	Donald Deitman	0
Common Stock	Robert F. Schaul, Esq.	274,286(6)
Common Stock	Mohammed Abd El-Shafy	150,000(7)
Common Stock	William F. Hamilton, Ph.D.	0(8)
Common Stock	Lawrence J. Kessel, M.D., FACP	0(8)

Common Stock	Barry Cohen	0(9)
Common Stock	Mark H. Rachesky	833,334(10)
Common Stock	Charles Nemeroff, M.D., Ph.D.	0(11)
Common Stock	Lindsay Rosenwald	13,233,334(12)
Common Stock	Biomedical Investment Group, LLC	5,333,334 (12)(13)
Common Stock	All Executive Officers and Directors as a group (11 persons)	4,028,289 (2)(3)(4) (6)(7)(8)(9) (10) (11)

(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; 152,000 shares owned by his daughter Christina Dugger; and 152,000 shares owned by his son Andrew Dugger.

(3) Does not include 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.

(4) Represents 333,333 Non-Plan Options exercisable at $2.40 per share. Does not include additional Non-Plan options to purchase 666,667 shares of common stock at an exercise price of $2.40 per share. These additional options vest in two equal installments in February 2004 and 2005. All of the options expire in 2012.

(5) Mr. Galler was granted Non-Plan options to purchase 1,050,000 shares of

common stock, at an exercise price of $0.75 per share. 700,000 of the options expire in September 2011; the remainder of 350,000 expire in December 2011.

(6) Includes: 20,000 options, issued under the 1992 Option Plan, to purchase common stock at an exercise price of $.63 per share, expiring in July, 2006; 25,000 options issued under the 1997 Option Plan, to purchase common stock at an exercise price of $.63 per share, expiring in March 2008; 10,000 options issued under the 1998 Option Plan, to purchase common stock at an exercise price of $.63 per share, expiring in September 2009: 95,000 options issued under the 1998 Option Plan, to purchase common stock at an exercise price of $.63 per share, expiring in January 2010; 75,000 options issued under the 1998 Option Plan, to purchase common stock at an exercise price of $2.69 per share, expiring in February 2012; and, 10,000 options issued under the 1998 Option Plan to purchase common stock at an exercise price of $1.51 per share, expiring in March 2008.

(7) Includes Non-Plan Options exercisable at $3.02 per share; does not include additional Non-Plan Options to purchase 50,000 shares of common stock at an exercise price of $3.02 per shar,. which additional options vest in May 2004. All of such 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.

(8) Does not include options to purchase 100,000 shares of common stock at an exercise price of $1.51 per share, which shall vest in three annual installments beginning March 2004.

(9) Does not include 75,000 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.

(10) Does not include options to purchase 100,000 shares of common stock at an exercise price of $2.15 per share, which shall vest in three annual installments beginning June, 2004. Includes 666,667 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.

(11) 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.

(12) 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 March 2009, owned by Biomedical Investment Group, LLC, which is an affiliate of Lindsay A. Rosenwald.

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

Shareholder Approval of Equity Compensation Plans

The following table sets forth information as of the end of fiscal 2003 with respect to the number of shares of the Company's Common Stock issuable pursuant to equity compensation plans which have and have not been approved by 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 NovaDel was or is 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 Lindsay 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 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 Board meetings. Appropriate confidentiality agreements are in place to protect confidential company 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 LLC, which is affiliated with Dr. Rosenwald. These warrants expire in March 2009.

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. (Manhattan) for the worldwide, exclusive rights to out lingual spray technology to deliver Propofol for pre-procedural sedation. The terms of the agreement call for certain milestones and other payments, the first of which was received during June 2003. One of the Company's Affiliates, Dr. Lindsay Rosenwald, is also an Affiliate of Manhattan. Manhattan is a development stage company and has no revenues to date. The agreement has conditions that stipulate that Manhattan can achieve this. If Manhattan is

unable to raise additional funds, there is significant doubt it would be able to fulfill its remaining commitments to the Company. See also Notes 6 and 7 to the Financial Statements.

During fiscal 2003 the Company paid Mr. Schaul approximately $160,000 for legal services rendered to the Company.

PART IV

ITEM 13. EXHIBITS LIST AND REPORTS ON FORM 8-K

(a) (1) The following financial statements are included in Part II, Item 7:

INDEPENDENT AUDITORS'S REPORT

To the Audit Committee of NOVADEL PHARMA INC.

We have audited the balance sheet of NOVADEL PHARMA INC., formerly known as Flemington Pharmaceutical Corporation as of July 31, 2003, and the related statements of operations, changes in stockholders' equity and cash flow for each of the two years in the period 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 auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements. 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 the results of its operations and its cash flows for each of the two years in the period then ended, are in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has had a recent history of recurring losses from operations, giving rise to an accumulated deficit through July 31, 2003, and is currently developing pharmaceutical products which will require

substantial financing to fund anticipated product development costs. Resulting operating losses and negative cash flows from operations are likely to occur until, if ever, profitability can be achieved through successful marketing of newly developed products. These factors raise substantial doubt about the Company's ability to continue as going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ WISS & COMPANY, LLP

WISS & COMPANY, LLP

Livingston, New Jersey
September 8, 2003

NOVADEL PHARMA INC.

BALANCE SHEET
JULY 31, 2003

ASSETS

CURRENT ASSETS:		
Cash and equivalents	$ 3,086,000	
Accounts receivable - trade	2,000	
Prepaid expenses and other current assets	168,000	
Total Current Assets		$
FURNITURE, FIXTURES, EQUIPMENT and LEASEHOLD IMPROVEMENTS, LESS ACCUMULATED DEPRECIATION OF $252,000		
OTHER ASSETS		

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:		
Accounts payable-trade	$ 139,000	
Accrued expenses and other current liabilities	318,000	
Total Current Liabilities		$
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		

Preferred stock, $.01 per value:	
Authorized shares, none issued	1,000,000
Common stock $.001 par value:	
Authorized - 50,000,000 shares	
Issued and outstanding -17,972,760 shares	18,000
Additional paid-in capital	19,480,000
Accumulated Deficit	(15,628,000)
Total Stockholders' Equity	

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
STATEMENT OF OPERATIONS

	Year Ended July 31,	
	2003	2002
CONSULTING REVENUES	$ 2,000	$ 339,000
CONSULTING, RESEARCH AND DEVELOPMENT EXPENSES	1,048,000	962,000
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,902,000	3,767,000
LOSS FROM OPERATIONS	(5,948,000)	(4,390,000)
BUY-OUT OF CONSULTANT'S CONTRACT	--	(32,000)
INTEREST INCOME	49,000	44,000
NET LOSS BEFORE TAXES	(5,899,000)	(4,378,000)
DEFERRED STATE INCOME TAX BENEFIT	84,000	88,000
NET LOSS	$ (5,815,000)	$ (4,290,000)
BASIC AND DILUTED LOSS PER COMMON SHARE:		
Net Loss	$ (.38)	$ (.38)

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	15,419,000	11,361,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock			
	Shares	Par Value	Additional Paid-in Capital	A
BALANCE, JULY 31, 2002	14,448,817	$14,000	$13,322,000	
YEAR ENDED JULY 31, 2003				
Common Shares Issued in connection with private placements, net of costs	3,200,345	3,000	4,333,000	
Shares issued for Options exercised	210,577	-	-	
Shares issued for Warrants exercised	113,021	1,000	19,000	
Options issued for services	-	-	1,674,000	
Warrants issued for services	-	-	7,000	
Equity investment from related party	-	-	125,000	
Net Loss	-	-	-	
BALANCE, JULY 31, 2003	17,972,760	$18,000	$19,480,000	$

See accompanying notes to financial statements.

NOVADEL PHARMA INC
STATEMENT OF CASH FLOWS

	July 31 Year Ended	
	2003	20
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$(5,815,000)	$(4,2
Adjustments to reconcile net loss to net cash flows from operating activities:		

Options issued for services	1,674,000	1,9
Warrants issued for services	7,000	
Depreciation and amortization	81,000	
Allowances for Doubtful Accounts	(88,000)	
Changes in operating assets and liabilities:		
Accounts receivable	87,000	
Demand note receivable, Officer	--	
Prepaid expenses and other current assets	(72,000)	(
Due from Joint Venture partner for reimbursable expenses	--	
Other Assets	(335,000)	
Accounts payable - trade	14,000	1
Accrued expenses and other current liabilities	127,000	1
Net cash flows from operating activities	(4,320,000)	(1,8
CASH FLOWS FROM INVESTING ACTIVITIES -		
Purchase of property and equipment	(389,000)	(3
Net cash flows from investing activities	(389,000)	(3
CASH FLOWS FROM FINANCING ACTIVITIES -		
Proceeds received from the exercise of warrants	20,000	
Proceeds received from private placements	4,336,000	4,9
Capital contributions from related party	125,000	
Net cash flows from financing activities	4,481,000	4,9
NET CHANGE IN CASH	(228,000)	2,7
CASH, BEGINNING OF YEAR	3,314,000	5
CASH, END OF YEAR	3,086,000	$ 3,3
SUPPLEMENTAL CASH FLOW INFORMATION:		
Interest paid	$ --	$
Income taxes paid	$ --	$

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 patent-pending 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 and is also engaged in domestic and international consulting activities. Management intends to develop the products in collaboration with pharmaceutical companies.

Revenues and Costs - Consulting revenues from contract clinical research are recognized as earned.

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.

Cash Equivalents - Cash equivalents include certificates of deposit and money market instruments purchased with original maturities of three months or less.

Financial Instruments - Financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values. The fair value estimates presented here in were based on market or other information available to management. The use of different assumptions and/or estimation methodologies could have a material effect on the estimated fair value amounts.

Furniture, Fixtures, Equipment and Leasehold Improvements - Furniture, fixtures, equipment and leasehold improvements are stated at cost. The Company provides for depreciation using accelerated methods, based upon estimated useful lives of 5 to 7 years for furniture, fixtures, equipment and leasehold improvements over the useful life of the lease term, if shorter, for leasehold improvements.

Advertising - The Company expenses advertising costs when they are incurred. The Company did not incur advertising expenses in 2003 and 2002.

Research and Development Costs - All 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. The Company has incurred research and development expenses that totaled $660,000 and $606,000 for 2003 and 2002, respectively.

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. The Company received $84,000 and $88,000 in 2003 and 2002, respectively from the transfer of New Jersey Net operating losses (See Note 8).

Defined Contribution Retirement Plans - The Company has a

Simple IRA retirement plan, available to all employees, providing for contributions at management's discretion. During the years ended July 2003 and July 2002, the Company made contributions to the retirement plan of approximately $15,000 and approximately $11,000, respectively.

Risk Concentrations:

(a) Credit Risk - The Company maintains its cash balances in financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC) up to $100,000 each. Such balances during the fiscal year ended 2003 have exceeded the FDIC limits.

(b) Major Customers - During fiscal 2003, the Company had revenue from one customer located in the USA approximating 100% of the Company's total revenue.

During fiscal 2002, the Company had revenue from two customers located in the United States approximating 46 % and 40 %, respectively, of the Company's total revenue.

(c) Supplier Dependence - The Company believes that certain raw materials, including inactive ingredients, are available only from a limited number of suppliers internationally and that certain packaging materials intended for use in connection with its spray products currently are available from limited supply sources. The Company does not believe it will encounter difficulties in obtaining inactive ingredients or packaging materials necessary for the manufacture of its products. However, there can be no assurance that the Company will be able to enter into satisfactory purchasing agreements or arrangements, thereby, causing a potential significant adverse effect on the Company's ability to arrange for the manufacture of formulated products.

Use of Estimates - The preparation of financial statements in conformity with generally accepted accounting principles requires 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 (SFAS) No. 128, "Earnings Per Share" requires the disclosure of both diluted and basic earnings per share. Basic earnings per share is based on the weighted average of all common shares outstanding. The computation of diluted earnings per share does not assume the conversion, exercise or contingent issuance of securities that would have an antidilutive effect on earnings per share.

	2
Numerator:	
Net loss applicable to common shareholders - basic and diluted	(5,
Denominator:	
Denominator for basic earnings (loss) per common share:	
Weighted average shares	15
Effect of dilutive securities	
Denominator for basic and diluted earnings (loss) per common share	15
Earnings (loss) per common share:	
Basic and Diluted	

The Company uses the intrinsic value method prescribed by APB Opinion No. 25 to measure compensation expense. If the fair value method had been used to measure compensation expense as prescribed by SFAS No. 123, net loss would have increased by $486,000 or $.03 per share to $6,301,000 or $.41 per share for fiscal 2003. Net loss would have increased by $1,440,000 or $.13 per share to $5,730,000 or $.51 per share for fiscal 2002.

Recent Accounting Pronouncements -In November 22, 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 flow.

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.

Note 2 - Management's Plans to Overcome Operating and Liquidity Difficulties

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company's continued existence is dependent upon its ability to achieve profitable operations or obtain additional financing. The Company is currently seeking collaborative arrangements with pharmaceutical companies for the joint development of delivery systems and the successful marketing of these delivery systems. The Company is exploring merger

opportunities or other strategic alternatives to fund future operations.

In view of the Company's very limited resources, its anticipated expenses and the competitive environment in which the Company operates, there can be no assurance that its operations will be sustained for the duration of its next fiscal year.

Note 3 - Other assets and Accrued expenses:

Other assets - Approximately $352,000 of security deposits are included in the $357,000 total. The remainder is other assets.

Accrued expenses and other current liabilities - Approximately $76,000 of accrued payroll and related payroll taxes; $150,000 of accrued employee vacation, $32,000 of other expenses and $33,000 of accrued legal and professional fees are included in the $318,000 total. The remainder is other accrued expenses and other current liabilities.

Note 4 - Furniture, Fixtures and Equipment and Leasehold Improvements

Furniture, fixtures, and leasehold improvements equipment is summarized as follows:

	July 31, 2003
Equipment	$ 713,000
Furniture and fixtures	122,000
Leasehold improvements	131,000
	966,000
Less: Accumulated depreciation	252,000
	$ 714,000

Note 5 - Stockholders' equity:

Private Placement - 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 sixty six thousand, six hundred, sixty six and two thirds (66,666?) common shares, par value $.001, and sixteen thousand, six hundred, sixty six and two thirds (16,666?) 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).

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 to date. 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 6 - Related Party Transactions:

License & Development Agreement- In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. for the worldwide, exclusive rights to the Company's proprietary lingual spray technology (see Note 7). One of the Company's major shareholders is also a significant shareholder in Manhattan Pharmaceuticals, Inc.

The terms of the agreement require Manhattan Pharmaceuticals, Inc. (Manhattan) to make payments to the Company based on achieving certain conditions and milestones. The Company received $125,000 of a $250,000 non-refundable up-front licensing fee under the terms of the agreement. The Company recorded this amount as additional paid-in-capital. The remaining $125,000 has not been collected. Manhattan is a development stage company and has no revenues to date. The agreement has conditions that stipulate that Manhattan has to raise certain funds before the Company receives the remaining license fee. There is no assurance that Manhattan can achieve this. If Manhattan is unable to raise additional funds, there is significant doubt it would be able to fulfill its remaining commitments to the Company.

Legal Fees - The Company has incurred legal fees with an officer and director of the Company. These fees approximated $160,000 and $125,000 for the years ended July 31, 2003 and 2002, respectively.

Consulting Agreement - In February 2002 the Company entered into a consulting agreement with John H. Klein, effective February 1, 2002. In addition, in February 2002, Mr. Klein was elected as a member and Chairman of the Company's Board of Directors (see note 7). The Company believes Mr. Klein's extensive and successful experience in the pharmaceutical industry brings a strong benefit to the Company's Board.

Note 7 - Commitments and Contingencies:

Employment Agreements - In December 2002, Dr. Shangold entered into a three-year employment agreement with NovaDel pursuant to which he agreed to serve as its 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) invested in, or earned by, NovaDel during his term. We paid Dr. Shangold a contractual bonus of $200,000 during the fourth quarter. The investment bonus shall be reduced by certain proceeds received by Dr. Shangold from his former employer. 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.

In February 2002, effective January 1, 2002, the Company entered into an employment agreement with its then President for a base annual salary of $248,500. The agreement provides for annual cost of living adjustments equal to the greater of the increase in the Consumer Price Index or 5% with additional increases and bonuses as shall be approved by the Board. The agreement has a base term of three years, which became effective in January 2002. The agreement is thereafter renewable for additional one-year periods, unless the Company gives notice to the contrary.

In February 2002, the Company entered into a consulting agreement with its Chairman for a base annual retainer of $300,000, plus reimbursement of various expenses and certain success fees. The agreement has a base term of one year, which became effective in February 2002. The agreement is thereafter renewable for additional one-year periods, unless the Company gives notice to the contrary. In addition, the agreement granted the consultant 1,000,000 non plan options to purchase shares of the Company's common stock at an exercise price of $2.40 per share; as of the date of this report none of such options had vested.

In February 2002, effective January 1, 2002, the Company entered into an employment agreement with its Chief Financial Officer for a base annual salary of $125,000. The agreement provides for annual cost of living adjustments equal to the greater of the increase in the Consumer Price Index or 5% with additional increases and bonuses as shall be approved by the Board. The agreement has a base term of three years, which became effective in January 2002. The agreement is thereafter renewable for additional one-year periods, unless the Company gives notice to the contrary.

In December 2001, effective the Company entered into an employment agreement with its Vice President Corporate Development for a base annual salary of $120,00, later increased by an amendment to $180,000. The agreement as amended has a base term of three years, which became effective in December 2001. The agreement is thereafter renewable for additional one-year periods, unless the Company gives notice to the contrary. In addition, the agreement granted the employee 1,050,000 non plan options to purchase shares of the Company's common stock at an exercise price of $0.75 per share; as of the date of this report 1,050,000 of such options had vested (see Note 10).

In May 2002, the Company entered into an employment agreement with its Vice President Formulation Development for a base annual salary of $110,000. The agreement provides for annual cost of living adjustments equal to the greater of the increase in the Consumer Price Index or 5% with additional increases and bonuses as shall be approved by the Board. The agreement has a base term of three years, which became effective in May 2002. The agreement is thereafter renewable for additional one-year periods, unless the Company gives notice to the contrary. In addition, the agreement granted the employee 150,000 non plan options to purchase shares of the Company's common stock at an exercise price of $3.02 per

share; as of the date of this report none of such options had vested.

In May 2003, the Company entered into a three-year employment agreement with Barry Cohen pursuant to which he agreed to serve as the Company's Vice President, New Business & New Product Development. The Company agreed to pay Mr. Cohen an annual base salary of $185,000. Pursuant to the agreement, Mr. Cohen was also granted Plan options to purchase up to 75,000 shares of the Company's common stock at an exercise price of $2.20 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 ten (10) years.

License and Development Agreement - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. 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 calls for certain milestone and other payments, the first of which was partially received during June 2003 (See Note 6).

Leases - In August 2000, the Company entered into a 5-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. Previously, the Company rented office space on a month to month basis. Rent expense for the Company totaled approximately $92,000 and $75,000 for the years ended July 31, 2003, and 2002 respectively.

In March 2003, the Company entered into a 10 year lease for approximately 31,500 sq. feet of office, laboratory, manufacturing and warehouse space. These premises are presently being fitted-out and some office space was occupied during September 2003. Additional occupancy should begin, in stages, during the 4th calendar quarter of 2003. During the first 5 years of the lease, the annual rent will be approximately $330,000 plus a proportionate share of real estate taxes and common areas. Beginning in the 6th year and continuing through the 10th year of the lease, the annual rent will be approximately $363,000 plus a proportionate share of real estate taxes and common areas.

Future minimum rental payments as follows:

Year Ending July 31,	
2004	$480,000
2005	$461,000
2006	$443,000
2007	$443,000
2008	$443,000
2009 and thereafter	$443,000

$2,713,000

Government Regulation - The development, manufacture and commercialization of pharmaceuticals are subject to extensive regulation by various federal and state government entities. The Company cannot determine the impact of government regulations on the development of its delivery systems.

Note 8 - Income Taxes:

No provision for current and deferred income taxes is required for the years ended July 31, 2003 and 2002.

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

	July 2003
Net operating loss carryforwards	$ 5,300,000
	5,300,000
Valuation allowance	5,300,000
Net deferred tax asset	$ --

The following is a reconciliation of income tax benefit computed at the 34% statutory rate to the provision for income taxes:

	2003
Federal Tax at statutory rate	$ 1,977,000
State Income Tax	349,000
Non deductible; options issued for services	(670,000)
Valuation allowance	(1,656,000)
	$ --

A valuation allowance is provided when it is more likely than not that some portion of the will not be realized. The Company has determined, based on the Company's prior history of recurring losses, that a full valuation allowance is appropriate at July 31, 2003 and 2002.

At July 31, 2003, the Company has federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately $15,500,000 and

$10,031,000, respectively, which can be used to offset current and future taxable income through the year 2024.

Deferred income tax benefit - During December 2002, the Company received approximately $84,000 as consideration for transferring approximately $1,116,000 of New Jersey net operating loss tax benefit to a third party corporation buyer. The Technology Tax Certificate Transfer Program for transferring net operating loss and R & D tax benefits is the responsibility of New Jersey Economic Development Authority. During December 2001, the Company received approximately $88,000 from this program.

Note 9 - Stock Options:

At July 31, 2003, the Company had three plans to 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 ("ISO's") under the Internal Revenue Code or as non-qualified options, under the 1992 and 1997 Plans is 500,000 shares each and 1,800,000 under the 1998 Plan. ISOs may be granted to employees and officers of the Company and non-qualified may be granted to consultants, directors, employees and officers of the Company. Options to purchase Company's common stock could 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 ten years from the date of grant. ISOs granted to a 10% or more stockholder could not be for less than 110% of fair market value or for a term of more than 5 years.

The Company follows the intrinsic 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 because, as discussed below, Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123) requires use of option valuation models that were not developed for use in valuing employee stock options. FAS 123 permits a company to elect to follow the intrinsic method of APR 25 rather than the alternative fair value accounting provided under FAS 123, but requires pro forma net income and earnings 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). Under APB 25, 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 was recognized.

Pro forma information regarding net income and earnings per share is required by FAS 123 and FAS 148, and has been determined as if the Company had accounted for its employee

stock options under the fair value method of that Statement.

The fair value of options granted in 2003 and 2002 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 74% in 2003 and 72% in 2002, and a weighted-average expected life of the options of five years.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective input assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of options is amortized to expense over the options' vesting period. The Company's pro forma information follows:

	Fiscal Ye June 30 2003
Net income (loss) as reported	$(5,815,000)
Stock-based employee compensation expense under fair value method, net of related tax effects	486,000
Pro forma net loss	$ (6,301,000)
Income / (Loss) per share:	
Basic and diluted, as reported	$(.38)
Basic and diluted, pro forma	$(.41)

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

	Outstanding Options	
Options Available for Grant	Number of Options	Weighted Exerci
---	---	---

Balance at August 1, 2001	--	2,300	$
Additional Shares reserved	2,475	--	
Grants	3,378	3,378	
Exercises	--	10	
Cancellations	1,190	1,190	
Balance at July 31, 2002	287	4,478	
Additional Shares reserved	2,575	--	
Grants	2,159	2,159	
Exercises	--	445	
Cancellations	--	--	
Balance at July 31, 2003	703	6,192	$

Option price per share: $.63 - $3.18
Options exercisable: 4,100,000

The following table summarizes significant ranges of outstanding and exercisable plan and non-plan options at July 31, 2003 (in thousands, except exercise price amounts):

	Outstanding Options			Options
Range of Exercise Prices	Options	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options
$0.01 - $1.00.....	2,035	6.9	$ .75	2,035
$1.01 - $2.00.....	2,395	4.1	1.77	1,195
$2.01 - $3.00.....	1,362	8.3	2.40	520
$3.01 - $4.00.....	400	8.7	3.12	350
	6,192	6.2	$1.66	4,100

In addition to stock options issued by the Company under the Plans, the Company has reserved 13,383,316 shares of common stock for non-plan options and warrants as detailed below.

Non-plan Options and Warrants - At July 31, 2003 there were outstanding the following classes and numbers of instruments exercisable for Common Stock:

A. 680,000 Class A Warrants, issued in connection with the Public Offering, exercisable until November 2003, to purchase a like number of shares of Common Stock at an exercise price of $5.80 per share. These warrants were originally scheduled to expire during November 2002. Before expiration, the Company extended the expiration date by one year, to November 2003. The Company has not yet made any decision as to whether the expiration date might be further extended.

B. 4,550,000 stock options, not issued under any of the plans, as follows:

- 300,000 options issued on November 19, 1997, vesting immediately, to the Company's then President, having an exercise price of $1.84 per share, issued in connection with his employment agreement in June 1997, exercisable until November 2007.

- 300,000 options issued on November 19, 1997, vesting immediately, to the Company's then Chairman, having an exercise price of $1.84 per share, issued in connection with his employment agreement in June 1997, exercisable until November 2007.

- 700,000 options issued in December 2001, and 350,000 options issued in July 2003, for a total of 1,050,000, vesting immediately, to the Company's Vice President for Corporate Development, in connection with his employment agreement, exercisable until December 2011.

- 1,000,000 options issued in February 2002, vesting in three equal installments beginning in February 2003, to the Company's present Chairman in connection with his consulting agreement, having an exercise price of $2.40 per share, exercisable until January 2012.

- 250,000 options issued in April 2002, vesting immediately, to a consultant to provide investment banking assistance to the Company. These options have an exercise price of $3.18 per share, exercisable until April 2012.

- 150,000 options issued in May 2002, vesting in three equal installments beginning November 15, 2002, to the Company's Vice President Formulation Development, in connection with his employment agreement, having an exercise price of $3.02 per share, exercisable until May 2012.

- 200,000 options issued in October 2002, to the Company's Chief Scientific Officer, having an exercise price of $1.30 per share, exercisable until October 2007.

- 1,000,000 options issued in December 2002, vesting in three equal installments beginning in December 2003, to the Company's present President, having an exercise price of $1.93 per share, issued in connection with his employment agreement, exercisable until December 2007.

- 100,000 options issued in March 2003, to each of two directors, for a total of 200,000, having an exercise price of $1.51 per share, exercisable until March 2008.

- 100,000 options issued in June 2003, to a director, having an exercise price of $2.15 per share, exercisable until June 2008.

C. 60,000 warrants issued to a public relations company, exercisable until January 2007 at a price of $2.00.

D. 4,000,000 warrants issued to an investor, in connection with the fiscal year 2002 private placement, exercisable until December 2008 at a price of $.75.

E. 2,666,667 warrants issued to an investor, in connection with the fiscal year 2002 private placement, exercisable until December 2009 at a price of $.75.

F. 200,000 warrants issued to a consulting company, exercisable until January 2010 at a price of $1.00.

G. 200,000 warrants issued to each of two consulting companies, for a total of 400,000, exercisable until November 2010 at a price of $.75.

H. 76,533 warrants at $.75 per share issued to broker/dealers in connection with the fiscal year 2001 private placement. 5,000 of such warrants expire in December 2008, and remaining warrants (71,533) expire in May 2011.

I. 210,017 warrants at $1.50 per share issued to broker/dealers in connection with the fiscal year 2003 private placement. 93,167 of such warrants expire in April 2008, and remaining warrants (116,850) expire in May 2008.

J. 40,004 warrants at $2.00 per share issued to broker/dealers in connection with the fiscal year 2003 private placement. 23,292 of such warrants expire in April 2008, and remaining warrants (16,712) expire in May 2008.

K. 800,095 warrants at $1.50 per share issued to investors in connection with the fiscal year 2003 private placement. 465,841 of such warrants expire in April 2008, and remaining warrants (334,254) expire in May 2008.

Note 10 - Subsequent Events:

In August 2003, Robert Galler agreed to terminate his employment with the Company as Vice President - Corporate Development and entered into a consulting agreement with the Company at a base compensation of $180,000 per year. The consulting agreement terminates in February 2005.

(a) (2) List of Exhibits

	Incorporated Documents	SEC Exhibit Refere
2.1	Agreement of Merger dated as of October 29, 1998	As filed with the Registrant's Pr Statement on October 20, 1998, Fi
3.1	Certificate of Incorporation of the Registrant, as amended	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
3.2	Bylaws of the Registrant, as amended	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
4.1	Form of Warrant Agreement	As filed with the Registrant's Fo October 31, 1997, File No. 333-33
4.3	Form of Class A Warrant Certificate	As filed with the Registrant's Fo October 31, 1997, File No. 333-33
4.4	Form of Underwriters' Option Agreement	As filed with the Registrant's Fo October 31, 1997, File No. 333-33
10.1	Employment Agreement with Harry A. Dugger, III, Ph.D.	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.2	Employment Agreement with John J. Moroney	As filed with the Registrant's Fo October 3, 1997, File No. 333-332
10.3	Agreement dated December 7, 1996 between the Registrant and Altana, Inc.	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.4	Registrant's 1992 Stock Option Plan	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.5	Form of Option Agreement under the 1992 Stock Option Plan	As filed with the Registrant's Fo October 3, 1997, File No. 333-332
10.6	Registrant's 1997 Stock Option Plan	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.7	Form of Option Agreement under the 1997 Stock Option Plan	As filed with the Registrant's Fo October 3, 1997, File No. 333-332
10.8	Agreement with Rapid Spray (Clemastine) Dated June 2, 1992	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.9	Agreement with Rapid Spray (Nitroglycerin) dated June 2, 1992	As filed with the Registrant's Fo August 8, 1997, File No. 333-3320
10.10	Agreement with Creative Technologies, Inc. dated December 26, 1996	As filed with the Registrant's Fo October 3, 1997, File No. 333-332
10.11	Registrant's 1998 Stock Option Plan	As filed with the Registrant's Pr Statement on October 20, 1998, File No. 000-23399
10.12	Employment Agreement with Donald P. Cox,	As filed with the Registrant's Fo

	Ph.D.	October 28, 1999, File No. 000-23
10.13	Employment Agreement with Kenneth Cleaver, Ph.D.	As filed with the Registrant's Fo October 28, 1999, File No. 000-23
10.14	Amendment to Consulting Agreement with Saggi Capital Corp. dated March 25, 1998	As filed with the Registrant's Fo October 28, 1999, File No. 000-23
10.15	Agreement with Altana, Inc., dated December 7, 1996	As filed with the Registrant's Fo September 26, 2001, File No. 000-
10.16	Agreement with CLL Pharma dated February 12, 1998	As filed with the Registrant's Fo September 26, 2001, File No. 000-
10.17	Agreement with Nace Resources, Inc., dated December 29, 1997, together with Amendment Number 1 dated February 9, 1998; Amendment Number 2 dated November 29, 1999; and, Amendment Number 3, dated May 5, 2000	As filed with the Registrant's Fo September 26, 2001, File No. 000-
10.18	Agreement with PolyMASC Pharmaceuticals on plc, dated July 25, 2000	As filed with the Registrant's Fo September 26, 2001, File No. 000-
10.19	Authorization to proceed with Innovex, Inc. and Novartis Pharmaceuticals Corp., dated June 15, 2000	As filed with the Registrant's Fo September 26, 2001, File No. 000-
10.20	Consulting Agreement with John Klein.	As filed with the Registrant's Fo 15,2002, File No. 333-86262
10.21	Employment Agreement with Robert Galler.	As filed with the Registrant's Fo 15,2002, File No. 333-86262
10.22	Employment Agreement Amendment No. 1 with Robert Galler	As filed with the Registrant's Fo 15,2002, File No. 333-86262
10.23	Employment Agreement with Donald Deitman.	As filed with the Registrant's Fo 15,2002, File No. 333-86262
10.24	Common Stock and Warrant Purchase Agreement dated December 12, 2001.	Incorporated by Reference to Sche December 21, 2001 by Lindsay A. R
10.25	Amendment No. 1 to Common Stock and Warrant Purchase Agreement	As filed with the Registrant's Fo 15,2002, File No. 333-86262
10.26	Employment Agreement with Mohammed Abd El-Shafy, Ph.D	As filed with the Registrant's Fo Amendment #2, on September 3, 200 333-86262
10.26	Employment Agreement with Gary A. Shangold, MD	As filed with the Registrant's Fo period ended January 31, 2003, Fi
10.27	Amendment No. 1 of Employment Agreement	As filed with the Registrant's Fo

	with Gary A. Shangold, MD	period ended January 31, 2003, Fi
10.28	Lease Agreement dated March 19, 2003, with Macedo Business Park, II, L.L.C	As filed with the Registrants' Fo period ended April 30, 2003, File
10.29	Amendment No. 1 of Lease Agreement dated March 19, 2003, with Macedo Business Park, 30, 2003, File No. 000-23399 II, L.L.C.	As filed with the Registrant's Fo period ended April
10.30	Employment Agreement with Barry C. Cohen	As filed with the Registrant's Fo period ended April 30, 2003, File
10.31	* Agreement with Manhattan Pharmaceuticals, Inc. dated April 4, 2003.	
11.1	* Computation of earnings per share	
23.1	* Consent of Wiss & Company LLP	
31.1	* Certification of Chief Executive Officer under Rule 13a-14(a)	
31.2	* Certification of Chief Financial Officer under Rule 13a-14(a)	
32.1	* Certification of Chief Executive Officer under 18 USC 1350	
32.2	* Certification of Chief Financial Officer under 18 USC 1350	

* Filed herewith

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the last quarter of fiscal 2003.

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

[This item is not yet effective.]

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: October 29, 2003 By: /s/ Gary A. Shangold

Gary A. Shangold, President

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report is signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Gary A. Shangold Gary A. Shangold	President and Chief Executive Officer (Principal Executive Officer) and Director	October 29
/s/ Donald J. Deitman Donald J. Deitman	Chief Financial Officer (Principal Financial Officer)	October 29
/s/ John H. Klein John H. Klein	Chairman of the Board and Director	October 29
/s/ Robert F. Schaul Robert F. Schaul	Secretary and Director	October 29
/s/ William F. Hamilton William F. Hamilton	Director	October 29
/s/ Lawrence J. Kessel Lawrence J. Kessel	Director	October 29
/s/ Mark H. Rachesky Mark H. Rachesky	Director	October 29
/s/ Charles Nemeroff Charles Nemeroff	Director	October 29