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NOVADEL PHARMA INC  
Form 10KSB  
November 13, 2002

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-KSB

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
For the fiscal year ended July 31, 2002

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.)

31 State Highway 12 Flemington, New Jersey

08822

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(Address of principal executive offices)

(Zip Code)

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

Indicate by check mark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Check if there is no disclosure of delinquent filings pursuant to Item 405 of Regulation S-B contained herein, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. .

State the issuer's revenues for its most recent fiscal year: \$339,000

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant at October 21, 2002 was approximately \$ 9,293,000 based upon the closing sale price of \$1.35 for

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the Registrant's Common Stock, \$.001 par value, as reported by the National Association of Securities Dealers OTC Bulletin Board on October 21, 2002.

As of October 21, 2002 the Registrant had 14,526,974 shares of Common Stock, \$.001 par value, outstanding.

Documents incorporated by reference: None

NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

Annual Report on Form 10-KSB  
For the Fiscal Year Ended July 31, 2002

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## PART I

### ITEM 1. BUSINESS.

#### General

NOVADEL PHARMA INC., a Delaware corporation ( "NovaDel" or the "Company") (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. The Company's (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. The Company's proprietary delivery system enhances and greatly accelerates the onset of the therapeutic benefits which the drugs are intended to produce. The Company refers to its delivery system as Immediate-Immediate Release (I2RTM) because its delivery system is designed to provide therapeutic benefits within minutes of administration. The Company's development efforts for its 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, the Company believes that its 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, the Company will seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. Due to the Company's small revenue base, low level of working capital and inability to include the number of development agreements with pharmaceutical companies, the Company has been unable aggressively to pursue its product development strategy. The Company will require significant additional financing and/or a strategic alliance with a well-funded development partner to undertake its business plan. See "Management Discussion and Analysis."

At its inception in 1982, the Company was a consultant to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992 the Company has used its consulting revenues to fund its own product development activities. The Company's focus on developing its own products evolved naturally out of its consulting experience for other pharmaceutical companies. Substantially all of the Company's revenues previously were derived from its consulting activities. In 1998, the Company changed the name under which it performed its consulting activities from Pharmaconsult to FPC Consulting. Effective October 1, 2002, the Company changed its corporate name from Flemington Pharmaceutical Corporation to Novadel Pharma Inc. The Company's principal business address is 31 State Highway 12, Flemington, New Jersey, 08822, and its telephone number is (908) 782-3431.

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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 December 2001 and February 2002, the Company successfully closed private placements of 4,000,000 shares and 2,666,667 shares, respectively, of its common stock, par value \$.001 per share, at a per share price of \$.75. In addition to the shares, the placement included an equal number of warrants to purchase additional shares in the same number at a price of \$0.75 per share. The Company received aggregate net proceeds of approximately \$4,916,000. See "Certain Relationships at Related Transactions".

### Product Development

The Company has the following products under active development, with clinical trials either having been performed or currently under way, pursuant to open INDs.

#### 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

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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. The company is presently seeking a partner to develop 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 the first 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 are planned. The company is seeking a partner to develop this product.

### Estradiol Sprays

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

### Business Strategy

The Company'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 the Company'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, the Company will seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. The Company's lack of working capital has impaired its ability to pursue its strategy. See "Management Discussion and Analysis."

### Patented and Patent Pending Delivery Systems

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NovaDel has certain patents and pending patent applications for its

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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. The Company'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. The Company 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

The Company'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(1)(b)(2) or Section 505(b)(2) of the FDC Act. An NDA submitted under these sections of the FDC Act are generally less complex than an ordinary NDA and are usually acted upon by FDA in a shorter period of time. It is the Company'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 the Company or its licensees will be making new claims as to therapeutic effects or lessened side effects, or both.

The Company 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 the Company'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."

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

\* Cardiovascular (Nitroglycerin)

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The Company'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. The Company anticipates filing an NDA in the first quarter of 2003.

### \* 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 is presently in progress. The Company anticipates filing an NDA in 2003.

### \* 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 the first 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 planned. The Company is seeking a partner to develop this product.

### Marketing and Distribution

The Company 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 Company'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. The Company will seek to position its proposed products as alternatives or as line extensions to brand-name products. The Company believes that to the extent that the Company'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 the Company does not have the financial or other resources to undertake extensive marketing activities, the Company generally intends to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties.

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The Company believes that such third-party arrangements will permit the Company to maximize the promotion and distribution of its products while minimizing the Company's direct marketing and distribution costs. Other than the Company's aforementioned agreements for the Company's proposed lingual spray products for angina, the Company 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. There can be no assurance that the Company's proposed products can be successfully marketed.

Strategies relating to marketing of the Company'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. The Company has no experience in marketing or distribution of its proposed proprietary products, and the Company's ability to fund such marketing activities will require the Company to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

### Manufacturing

The Company has determined to internalize the manufacturing of its proposed products. Presently, it has established a pilot manufacturing facility at its present location, which it believes is adequate for its needs in manufacturing its requirements for formulation development, stability testing and clinical supplies. It is also presently in negotiations for a new, larger facility which will have adequate space for its future foreseeable requirements for production manufacturing and warehouse space. There can be no assurance, however, that the Company will be successful in concluding such negotiations, or that it 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 the Company to make arrangements with a third party contract manufacturer to satisfy the Company's requirements. There can be no assurance that, if necessary, the Company will be able to do so, or be able to do so on commercially satisfactory terms. Failure of the Company to complete successfully the internalization of its manufacturing requirements, or to conclude an alternative contract manufacturing arrangement, could have an adverse effect on the Company's efforts to obtain regulatory approval for or to commercialize its products.

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

The manufacture of the Company'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."

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



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Accordingly, the Company 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 the Company 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 German marks), the operating results of the Company will be affected by fluctuations in foreign currency exchange rates.

### Raw Materials and Suppliers

The Company 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 the Company's lingual spray products may be only available from sole source suppliers. Although the Company 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 the Company 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 the Company's pharmaceutical products are dependent upon the Company'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, the Company 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.

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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 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 four to seven years 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. The Company believes that products developed in lingual spray delivery systems (dosage forms) usually will require submission of an NDA under Section 505(b)(2).

The Company 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 are usually acted upon by the FDA in a shorter period of time. There can be no assurance that the Company'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 the Company'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 the Company intends to enter are characterized by intense competition. The Company will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those the Company 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 the Company's proposed products. The Company 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 the Company has targeted for development are intensely competitive, involving numerous competitors and products. The Company will seek to enhance its competitive position by focusing its efforts on its novel dosage forms.

#### Patents and Protection of Proprietary Information

The Company has applied for United States and foreign patent protection for the delivery system which is the primary focus of its development activities as well as the 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 any adequate protection to the Company. The Company 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 patent or similar rights with respect thereto.

Although the Company 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, the Company could, under certain circumstances, be required to modify the infringing process or obtain a license. There can be no assurance that the Company 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 the Company and its business. In addition, there can be no assurance that the Company will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. If any of the products developed by the Company infringe upon the patent or proprietary rights of others, the Company could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on the Company.

The Company 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 the Company 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 the Company.

Buccal Nonpolar Spray. On April 12, 1996 the Company filed an application with the United States Patent and Trademark Office ("PTO") for protection of this subject matter. On September 1, 1998 the PTO allowed the claims directed to sprays, but rejected the claims directed to the capsules. In October 1998 the Company dropped the capsule claims from this application, to pursue allowance and issuance of a patent directed to the spray claims. On October 21, 1999 the PTO issued a patent to the Company on the spray claims (#5955098).

On February 21, 1997, the Company filed an application under the Patent Cooperation Treaty ("PCT") for the above-subject matter. The International Preliminary Examination Authority has issued an opinion in which the PCT examiner determined that the subject matter of the invention while novel, is not inventive for obviousness.

This opinion, with which the Company disagrees, is not dispositive, however, it may be highly persuasive in subsequent proceedings in the European and individual national patent offices should the Company decide to proceed in these jurisdictions.

In October 1998, the Company filed a patent application in the European Patent Office and in Canada for the buccal nonpolar spray claims. The former has not yet been acted upon; the latter is not yet due for examination.

Buccal Polar Spray. On April 12, 1996, the Company filed an application in the PTO directed to the buccal polar spray. The PTO allowed the claims directed to sprays, but rejected the claims directed to the capsules. The Company dropped the capsule claims from this application, to pursue allowance and issuance of a patent directed to the spray claims and subsequently the PTO issued a patent to the Company on the spray claims. In October 1998, the Company filed a patent application in Canada for the buccal nonpolar spray claims.

On February 21, 1997 the Company filed a PCT application directed to the foregoing subject matter. The situation with respect to this subject matter is the same as that of the counterpart PCT application directed to buccal nonpolar spray or capsule discussed above. The Company has dropped the two bite capsule parts and individually filed for patent protection in Canada and Europe for the three spray inventions.

In October and November 1998, the Company filed patent applications in Europe and Canada for the buccal polar spray claims. In the former case an Official action has been received and responded to. The latter is not ripe for examination yet.

Buccal Nonpolar Spray for Nitroglycerin. On April 12, 1996, the Company filed an application in the PTO directed to the above subject matter; no claims were allowed. On November 25, 1998, the Company filed the application in the PTO, directed to the method of use of the spray. Subsequently, the PTO issued a patent (#5869002) on those claims. On February 21, 1997, the Company filed a PCT application directed to the above subject matter. The application was rejected for lack of inventive step on the ground that the manner in which the claims differed from the prior art was required by legislation. European and Canadian counterpart applications have been filed. The Canadian application is not yet ripe for examination.

Buccal/Polar/Nonpolar Sprays or Capsule (Different Medicaments as Above). An application was filed with the PCT on October 1, 1997 designating a large number of possible countries including the United States. This application differs from the first two applications above in that it utilizes different ingredients. The PCT Examiner allowed two rather limited (but not commercially insignificant) claims and rejected the remaining claims for lack of inventiveness and lack of unity. The Company has made individual filings for patent protection in USA, Japan, Canada, and Europe.

In the United States, the original application has been refiled as a CIP (008) directed only to pump spray compositions. An initial Official Action has been received and responded to. No examination is yet due in Japan and Canada. Upon advice of our European Associate, the original application was filed as three separate divisional applications. While some

new references have been cited no Official Action has been received in any of these cases.

Antihistamine Syrup and Ointment. On November 10, 1997 the Company filed an application with the U.S. PTO for protection of its antihistamine syrup and ointments, a technology to be used in the Company's proposed poison ivy product. In October 1998, the PTO initially rejected the application, which was then refilled in May 2000 with claims directed solely to method of protection. On May 21, 2002 the PTO granted the Company's patent application.

General Comment with Respect to the Foregoing PCT Applications. The Company is interested in obtaining patent protection in Europe and Canada. It is to be expected that the same examiner who examined these applications as a PCT examiner will be the examiner who will handle these applications in the European "National" Phase. Hence, the Company anticipates that in the case of the European applications, it may be necessary to appeal to the Board of Appeals in Munich. At the present time, it is not possible accurately to predict the expenses involved in pursuing the foregoing applications. However, expenses may exceed \$100,000 (in the aggregate for all three applications) before a final disposition is obtained. The Company expects this process to take between two and four years.

#### Product Liability

The Company may be exposed to potential product liability claims by consumers. The Company does not presently maintain product liability insurance coverage. Although the Company will seek to obtain product liability insurance prior to the commercialization of any products, there can be no assurance that the Company 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 the Company, insufficiency of insurance coverage could have a material adverse effect on the Company. 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 the Company 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 the Company.

#### Customer Dependence

Since inception, substantially all of the Company's revenues have been derived from consulting activities primarily in connection with product development for various pharmaceutical companies. Among other things, the Company worked with its European clients to obtain regulatory approvals for new drug formulations in the United States. As the Company has increasingly concentrated its attention and activities on developing its own products, its consulting activities have diminished. For the year ended July 31, 2002, consulting activities relating to the Company's two (2) largest clients accounted for approximately 46.2% and 39.3% respectively, of the Company's revenue. For the year ended July 31, 2001, consulting activities relating to the Company's two largest clients accounted for approximately 40% and 18% respectively, of the Company's revenue.

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### Employees

The Company currently has fifteen (15) full-time employees, four (4) of whom are executive officers of the Company, seven (7) of whom are laboratory or support personnel and four (4) 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

We had an accumulated deficit at July 31, 2002 of approximately \$9,813,000. We incurred operating losses in all of the last fiscal years ended July 31 including a net loss of approximately \$4,290,000 for the year ended July 31, 2002. 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, the Company's auditors have qualified their audit opinion with regard to the Company's 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 2001 and 2002 private placements and projected cash flow from operations will be sufficient to satisfy our contemplated cash requirements for at least 5 months from the date of this report. 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.

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See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

We are dependent on principal clients

To date, substantially all of our revenues have been derived from consulting services rendered to a limited number of clients, the loss of certain of which would have an adverse effect on us. For the year ended July 31, 2002, consulting activities relating to our two (2) largest clients, with which we have written agreements, accounted for approximately 46%, and 40% respectively, of our revenues. There can be no assurance that our clients will continue to seek consulting services from us or that we will continue to provide consulting services to the industry. See "Business- Customer Dependence."

Our business is evolving

Although we have received revenue from our own product development activities, these revenues are insignificant as compared to our revenues from product development consultation work done for our clients. The nature of our revenue received from our own product development consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials, and similar milestone-related payments. Subject to additional funding, we expect to continue our consulting activities despite increasing our product development activities. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for, and license out or market, our own 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 2003 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."

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We have not completed product development

The development of our proposed products has not been completed and we

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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 2003 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.

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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



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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 us. Moreover, many of these companies possess greater marketing capabilities than us, 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

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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.

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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 DNA for the previously approved drug. We believe that some of our drug products developed in capsule form will be substantially similar to products which have previously obtained FDA approval and, accordingly, that approvals for such products can be obtained by submitting an ANDA. We, however, may be required, before submitting an ANDA, to submit a suitability petition, the purpose of which is to permit the FDA to evaluate whether a change in strength, dosage form or method of delivery is significant enough to require clinical trials and, therefore, an NDA filing. There can be no assurance that the FDA will not require us to conduct clinical trials for such products and otherwise comply with the NDA approval process. 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 three to five years for the ANDA process and 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.

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We are dependent on existing management

Our success is substantially dependent on the efforts and abilities of our founder, President and Chief Executive Officer, Harry A. Dugger, III, Ph.D., our Chairman, John Klein, and our Chief Financial Officer, Donald

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Deitman. 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

Management and our affiliates currently beneficially own (including shares they have the right to acquire) approximately 83% of our common stock. These persons are and will continue to be able to exercise control over the election of our directors and the appointment of officers, increase the authorized capital, dissolve, merge or engage us in other fundamental corporate transactions.

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 than 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 were due to expire on November 18, 2002. In November 2002, the Company decided to extend their expiration date for a period of one year (i.e. to November 18, 2003). All other provisions of the warrants remain unchanged.

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 fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

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

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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

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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

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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, 2002 there were 14,448,817 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 13,110,281 shares of our common stock for issuance upon exercise of stock options and warrants. Of the reserved shares, a total of 2,075,000 shares have been reserved among NovaDel's 1992, 1997 and 1998 Stock Option Plans, of which options to purchase an aggregate of 500,000, 500,000 and 787,500 shares have been issued under the respective Plans. Another 2,800,000 shares are reserved for issuance and available for the options granted pursuant to the terms of the employment agreements of Mr. Moroney, a former director, Dr. Dugger, our CEO, Robert Galler, a director, and John Klein, our chairman and Mohammed El-Shafy, Vice President of Formulation Development. All 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 14,448,817 shares of common stock (as of July 31, 2002) held by our present stockholders, 7,774,385 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.

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Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an affiliate of the Company and who has satisfied a two-year holding period.

We have reserved up to 13,110,281 shares of common stock for issuance

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upon exercise of various stock options and warrants, of which 1,600,000 shares were registered under a Registration Statement on Form S-8 under the Act (with the balance registered under a registration statement of which this prospectus forms a part). Although all of our officers and directors have executed lock-up agreements in which they agreed not to publicly offer, sell or otherwise dispose of directly or indirectly, any of our securities owned by them, until December 2002 (except that 75% of each such person's shares have already been released and that on December 12, 2002, all of each such person's remaining shares become released from such lock-up), any substantial sale of common stock pursuant to Rule 144 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

The Company's executive offices are located at 31 State Highway 12, Flemington, New Jersey. The facility, constituting approximately 4,500 square feet is occupied under a five-year lease which expires during September 2005. During fiscal 2002, the Company paid rent of \$63,000 plus real estate taxes. Should this tenancy be terminated for any reason, there is ample comparable space available in the area for the Company to occupy. The Company presently is exploring relocation to larger facilities.

## ITEM 3. LEGAL PROCEEDINGS

The Company is not involved in any legal proceedings.

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## 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.

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PART II

ITEM 5. MARKET FOR COMMON STOCK AND RELATED SECURITYHOLDER 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". Prior thereto, 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 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 31, 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 |
| FISCAL 2000  |            |      |
| First Quarter (August 1, 1999 through October 25, 1999)    | 1.687      | .875 |
| Second Quarter (November 1, 1999 through January 31, 2000) | 2.25       | .875 |
| Third Quarter (February 1, 2000 through April 30, 2000)    | 3.375      | 1.00 |
| Fourth Quarter (May 1, 2000 through July 31, 2000)         | 1.406      | .750 |

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The closing bid price of the Company's Common Stock as reported by the

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OTCBB was \$1.35 on October 21, 2002.

(b) Holders. As of October 21, 2002 there were approximately 67 record holders of the Company's Common Stock.

(c) Dividends. The Company has never declared or paid a dividend on its Common Stock, and management expects that all or a substantial portion of the Company's future earnings will be retained for expansion or development of the Company's business. The decision to pay dividends, if any, in the future is within the discretion of the Board of Directors and will depend upon the Company's earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management does not anticipate that the Company 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. During the fourth quarter of fiscal 2002, a total of 49,485 shares of the Company's Common Stock was issued in connection with the cashless exercise of 67,358 warrants.

### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 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, 2002 of approximately \$9,813,000. 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, 2002 (fiscal 2002) and 2001 (fiscal 2001) and had an accumulated deficit at July 31, 2002 of approximately \$9,813,000.

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

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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.



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### Results of Operations

#### Fiscal Year 2002 Compared to Fiscal Year 2001

Consulting revenues for fiscal 2002 increased approximately \$39,000 or 13% to \$339,000 from \$300,000 for fiscal 2001. This revenue increase for fiscal 2002 was primarily attributable to an increase in project management of clinical studies for clients.

Consulting expenses increased approximately \$271,000 or 39% to \$962,000 from \$691,000 for fiscal 2001. This increase was due to increased payroll and inside laboratory expenses. Selling, general and administrative expenses increased approximately \$2,980,000 or 379% to \$3,767,000 from \$787,000 for fiscal 2001. This increase was due, primarily, to the value of options issued for services and had no effect on the Company's cash position.

Total costs and expenses for fiscal 2002 increased approximately \$3,251,000 or 220% to approximately \$4,729,000 from approximately \$1,478,000 for fiscal 2001.

This increase includes approximately: \$2,208,000 in outside consultant fees primarily due to options issued to consultants; \$288,000 in payroll expense primarily due to additional employees and the establishment of a vacation pay accrual; \$357,000 in legal & professional fees; \$131,000 in bad debt expense; \$92,000 in employee recruiting and relocation; \$51,000 in depreciation and amortization expense due to the earlier purchases of laboratory equipment; \$40,000 in laboratory expenses due to additional lab employees; \$34,000 in travel expenses; \$28,000 in public company expenses due primarily to an increase in the number of outside directors and the increased number of board meetings held during the 2002 Period; \$22,000 in trade show and conference expenses; \$19,000 in rent expenses due to increased rents for the Company's facilities, occupied in October 2000 and the establishment of the Company's Florida office during October 2001; \$19,000 in insurance expenses due to increased premiums for directors and officers coverage and additional clinical studies coverage; and, \$12,000 in outside services.

Decreases in costs and expenses for the 2002 Period, as compared to the 2001 Period, includes an approximate \$71,000 in laboratory testing and clinical studies costs due primarily to the Company's earlier decision to establish an internal laboratory.

A buy-out of a consultant's contract, during the 2002 Period, resulted in an approximate \$32,000 increase in expenses.

Interest income for fiscal 2002 increased approximately \$21,000 or 91% to \$44,000 from \$23,000 for fiscal 2001. The interest income increase was primarily attributable to an increased average cash balance in conjunction with reduced interest rates for the 2002 year.

Deferred income tax benefit for fiscal 2002 was approximately \$88,000 compared to approximately \$47,000 for fiscal 2001. These benefits resulted from the sale of the Company's New Jersey net operating losses.

The resulting net loss for fiscal 2002 was \$4,290,000 compared to a net loss of \$1,109,000 for fiscal 2001.

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### 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, 2002 the Company had working capital of approximately \$3,095,000 as compared to working capital of \$652,000 at July 31, 2001 representing a net increase in working capital of approximately \$2,443,000. During fiscal 2002, the Company successfully closed an offering of its securities ("Private Placement"). The Private Placement provided for the sale of approximately 6,667,000 shares of common stock, par value \$.001 per share. The Company received proceeds, net of offering costs, of approximately \$4,916,000.

Net cash used in operating activities was approximately \$1,871,000 for fiscal 2002 compared to net cash used in operating activities of approximately \$1,106,000 for fiscal 2001. Net cash used in operating activities for fiscal 2002 was primarily attributable to the net loss of \$4,290,000. For fiscal 2002, \$316,000 was used for investing activities. Therefore, notwithstanding a \$4,290,000 net loss and \$1,109,000 net loss for fiscal 2002 and 2001, respectively, total cash flow for fiscal 2002 increased approximately \$7,019,000 as compared to a \$994,000 increase for fiscal 2001.

The Company believes that its current cash levels together with revenues from operations, will be sufficient to satisfy its cash requirements for the next five (5) months. However, beyond this point there is substantial doubt about the Company's ability to continue operations without obtaining additional financing and/or consummating a strategic alliance with a well-funded business partner. There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside the control of the Company. We may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. These uncertainties raise substantial doubt as to the Company's ability to continue as a going concern. The Company's auditors have qualified their audit opinion with regard to the Company's ability to continue as a going concern.

### Inflation

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

### 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.

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

Not Applicable.

### PART III

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

The names and ages of 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<br>the Company                                | Principal<br>Occupation   | Director<br>Since |
|-----------------------------|-----|---|---|-------------------|
| Harry A. Dugger, III, Ph.D. | 66  | President and<br>Chief Executive<br>Officer                 | President and<br>Chief Executive<br>Officer of the<br>Company   | 1991              |
| John H. Klein               | 56  | Chairman  | Consultant  | 2002              |
| Robert F. Schaul, Esq.      | 65  | Secretary and<br>Director                                   | Attorney  | 1991              |
| Jack J. Kornreich           | 65  | Director  | Retired   | 1996              |
| Robert C. Galler            | 42  | Vice President,<br>Corporate<br>Development and<br>Director | Financial<br>Advisory<br>Services                               | 2001              |
| Donald J. Deitman           | 59  | Chief Financial<br>Officer                                  | Chief Financial<br>Officer of the<br>Company                    | -                 |
| Mohammed Abd El-Shafy       | 49  | Vice President,<br>Formulation<br>Development               | Vice President<br>Formulation<br>Development<br>for the Company | -                 |

Harry A. Dugger, III, Ph.D., President and Director. Dr. Dugger is a founder of the Company and has been President and a director of the Company since its inception in May 1982. Prior to founding the Company, 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

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2002 as a consultant and as Chairman of its Board of Directors. From April

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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 is 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. Mr. Klein is a member of the Board's Audit Committee.

Robert F. Schaul, Esq., Secretary and Director. Mr. Schaul has been a Director of the Company since November 1991 and was Vice President, Secretary and General Counsel of the Company from November 1991 to February 1995. He has advised the Company since its formation. 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.

Jack J. Kornreich, Director. Mr. Kornreich has been a director of the Company since 1996 and is a member of the Board's Audit Committee. He presently acts as an independent consultant. From 1989 to 1993, Mr. Kornreich was Executive Vice President and General Counsel of Bolar Pharmaceutical Corp. (now known as Watson Pharmaceutical Corp.). From 1984 to 1989, Mr. Kornreich practiced law as a partner in the firm of Baum & Kornreich (from 1980 to 1984 the firm was named Baum, Skigen & Kornreich). From 1975 to 1984, Mr. Kornreich was in private practice. Mr. Kornreich received a JD from Brooklyn Law School in 1963 and an LLM in Corporate Law from New York University in 1975.

Robert C. Galler, Vice President, Corporate Development and Director. Mr. Galler has been an employee and Director of the Company since September, 2001. From 1992 to the present, Mr. Galler has been the President and Chairman of the Lois Joy Galler Foundation for Hemolytic Uremic Syndrom, a non-profit charity. From 1999 to 2001, Mr. Galler was Vice President, Corporate Development and Director of Select Therapeutics, Inc. From 1994 to 1998 Mr. Galler was a Director and advisor of Synsorb Biotech, Inc. From 1992 to 1994 Mr. Galler was an equity coordinator at Gallers Financial Group, Inc., and from 1984 to 1992 he was Vice President of Investments with Gruntal & Co. Mr. Galler attended Hofstra University, Hempstead, N. Y.

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.

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Mohammed Abd El-Shafy, Ph.D. Dr. El-Shafy has been an employee of NovaDel since May of 2002. He serves as Vice President-Formulation Development. 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.

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, 2001 to July 31, 2002 all Section 16(a) filing requirements applicable to its Reporting Persons were complied with.

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 February 2002, Directors of the Company who are not employees or consultants receive fees of \$1,000 for each meeting of the Board of Directors or a committee of the Board attended. Such Directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board of Directors. Directors may be removed with or without cause by a vote of the majority of the stockholders then entitled to vote. There were no other arrangements pursuant to which any Director was compensated during fiscal 2002 for any services provided as a Director.

ITEM 10. EXECUTIVE COMPENSATION

#### EXECUTIVE COMPENSATION

The following table sets forth a summary for the fiscal years ended July 31, 2002, 2001 and 2000, 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 two most highly compensated officers other than the CEO, who served in such capacities at the end of fiscal 2002 (collectively, the "Named Executive Officers"). No other executive officer of the Company earned in excess of \$100,000 in total annual salary and bonus for 2000, 2001 and 2002 in all capacities in which such person served the Company. There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2000, 2001 and 2002 to the Named Executive Officers, except as set forth below:

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## SUMMARY COMPENSATION TABLE

| Name and<br>Principal<br>Position                              | Fiscal<br>Year | Salary<br>(\$) | Bonus<br>(\$) | Other<br>Annual<br>Compen-<br>sation<br>(\$) | Long-Term Compensation                |  |                         |        | All<br>Other<br>Compen-<br>sation<br>(\$) |
|--|----------------|----------------|---------------|--|---------------------------------------|--|-------------------------|--------|---|
|  |                |                |               |  | Awards                                |  | Payouts                 |        |   |
|  |                |                |               |  | Restricted<br>Stock<br>Awards<br>(\$) | Securities<br>underlying<br>Options/<br>SAR (1)<br>(#) | LTIP<br>Payouts<br>(\$) |        |   |
| Harry A. Dugger,<br>III, Ph.D.<br>President and CEO            | 2002           | 347,000<br>(2) | 0             | 0  | 0                                     | 0  | 0                       | 10,000 |   |
|  | 2001           | 182,974        | 0             | 0  | 0                                     | 0  | 0                       | 0      |   |
|  | 2000           | 226,000        | 0             | 0  | 0                                     | 95,000   | 0                       | 0      |   |
| John H. Klein<br>Chairman                                      | 2002           | 150,000        | 0             | 0  | 0                                     | 1,000,000  | 0                       | 36,000 |   |
| Donald Deitman (2)<br>Chief Financial<br>Officer               | 2002           | 104,400        | 0             | 0  | 0                                     | 0  | 0                       | 4,200  |   |
|  | 2001           | 70,800         | 0             | 0  | 0                                     | 0  | 0                       | 0      |   |
|  | 2000           | 68,000         | 0             | 0  | 0                                     | 0  | 0                       |        |   |
| Robert C. Galler<br>Vice President<br>Corporate<br>Development | 2000           | 143,600        | 0             | 0  | 0                                     | 700,000  | 0                       | 6,600  |   |

(1) No Stock Appreciation Rights have been issued.

(2) This amount exceeds the amount of annual compensation payable to Dr. Dugger under his employment agreement. The reason for this is that during fiscal 2002 Dr. Dugger was paid certain accrued compensation from a prior year.

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### OPTION GRANTS IN LAST FISCAL YEAR (individual grants)

The following table sets forth information with respect to the Named Executive Officers concerning grants of options during fiscal 2002:

| Option/SAR Grants in Last Fiscal Year<br>Individual Grants |  |   |                                      |                    |
|--|--|---|--------------------------------------|--------------------|
| (a)  | (b)  | (c)   | (d)                                  | (e)                |
| Name   | Number of<br>Securities<br>Underlying<br>Options/SARs<br>Granted (#) | % of Total<br>Options/SARS<br>Granted to<br>Employees in<br>Fiscal Year | Exercise or<br>Base Price<br>(\$/Sh) | Expiration<br>Date |
| Harry A Dugger III, Ph.D                                   | 345,000  | 16%   | \$0.70                               | 14 Nov. 2011       |
| John H. Klein  | 1,000,000  | 47%   | \$2.40                               | 31 Jan. 2012       |
| Donald J. Deitman  | 0  | N/A   | N/A                                  | N/A                |
| Robert Galler  | 350,000  | 16%   | \$0.75                               | 4 Dec. 2011        |
|  | 350,000  | 16%   | \$0.75                               | 11 Dec. 2011       |

In September 2001, the Company entered into a short-term employment agreement with Robert Galler, who was appointed as Vice President - Corporate Development and a Director. That agreement provided for the issuance to Mr. Galler of options to purchase 700,000 shares of our common stock at an exercise price of \$.75 per share. Under the agreement, the vesting of these options was subject to the satisfaction of certain conditions precedent. In December 2001, the agreement with Mr. Galler was amended to recognize the accomplishment of the conditions. Among other things, the term was extended to three years, his compensation was increased, the options became vested, and he was granted an additional 350,000 options (on the same terms) which would become vested upon satisfaction of a condition in the amended agreement.

During November 2001, we cancelled and reissued certain options under the 1992, 1997 and 1998 Option Plans. An aggregate of 345,000 options were issued to each of Harry A. Dugger and John J. Moroney at an exercise price of \$.70 per share (110% of the market price), having a term of five years. An aggregate of 150,000 options were issued to each of Jack Kornreich and Robert Schaul at an exercise price of \$.63 per share (100% of the market price), having a term of ten years.

In February 2002, we entered into a consulting agreement with John H. Klein, who was simultaneously elected as our chairman of the Board. The agreement is for a term of one year. Under the agreement, Mr. Klein was granted options to purchase 1,000,000 shares of our common stock at an exercise price of \$2.40 per share. The options have a term of ten years and vest in three equal annual installments, beginning in February 2003.

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Option Plan; 37,500 to John J. Moroney, and 75,000 to each of Jack Kornreich and Robert Schaul. The options have an exercise price of \$2.63 per share and a term of ten years.

In May 2002, 150,000 non-plan options were issued to Dr. Mohammed Abd El-Shafy pursuant to an employment agreement. The options have an exercise price of \$3.02 per share, and vest in three equal annual installments.

### 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 2002 and the number and value of unexercised options held as of the end of fiscal 2002.

| Name of Executive Officer   | Number of Shares Acquired on Exercise | value Realized (\$) | Number of Securities Underlying Unexercised Options at Fiscal Year End; (Exercisable/Unexercisable) | Value of Unexercised in-the Money Options at Fiscal Year End (\$); (Exercisable Unexercisable) |
|-----------------------------|---------------------------------------|---------------------|---|--|
| Harry A. Dugger, III, Ph.D. | 0                                     | -                   | 645,000 / 0   | 345,000 / 0  |
| John H. Klein               | 0                                     | -                   | 0 / 1,000,000   | 0 / 0  |
| Robert C. Galler            | 0                                     | -                   | 700,000 / 0   | 665,000 / 0  |
| Donald Deitman              | 0                                     | -                   | -   | -  |

#### Employment Agreements and Change in Control Arrangements

Dr. Dugger. 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 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." In addition, Mr. Klein is entitled to certain success fees upon completion of corporate deals he introduces to NovaDel.

Robert C. Galler. In December 2001, we entered into a three year employment agreement with Mr. Galler, who was appointed Vice President - Corporate Development and elected to the Board of Directors. Pursuant to the agreement, he receives a base salary of \$180,000 per year. In addition, he was granted 1,050,000 non-plan options at \$.75 per share. See "Certain relationships and related transactions."



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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 provides 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 receives a base salary, for the first year, of \$110,000 (which increases each year by the greater of the CPI index or 5%). In addition, he was granted 150,000 non-plan options at \$3.02 per share.

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 1,075,000 shares of common stock, for a total of 2,075,000 shares. The 1997 Stock Option Plan is administered by Harry A. Dugger, III, Ph.D. and John Klein (as of March 27, 2002), 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, 2002, 500,000, 500,000 and 787,500 shares of our common stock was reserved for issuance pursuant to the 1992, 1997 and 1998 Plans, respectively. The exercise prices for the outstanding options reserved under the 1992 Plan range between \$.63 and \$2.00 per share; the exercise prices for the outstanding options reserved under the 1997 Plan 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 \$2.63 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, 2002, we had 2,700,000 non-plan options outstanding as follows: 600,000 options exercisable at \$1.84 per share; 700,000 options exercisable at \$.75 per share; 1,000,000 options exercisable at \$2.40 per share; 250,000 options exercisable at \$3.18 per share; and 150,000 options exercisable at \$3.02 per share.

#### Compensation Committee Interlocks and Insider Participation

Harry A. Dugger, III and John H. Klein serve as the members of the Company's Compensation Committee, which reviews and makes recommendations with respect to compensation of officers, employees and consultants, including the granting of options under the Company's 1997 Stock Option Plan. The 1992 and 1998 Stock Option Plans are administered by the entire Board. In the case of a conflict, Mr. Kornreich replaces the conflicted Compensation Committee member.

Robert F. Schaul, a Director and Secretary of the Company, earned legal fees from the Company during fiscal 2002 in the approximate amount of \$125,000. See "Certain Transactions--Legal Fees," below.

#### ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information, as of July 31, 2002 with respect to the beneficial ownership of the outstanding shares of our common stock (14,441,052 as of such date plus, where relevant for particular beneficial owners, shares which such beneficial owner has the right to acquire), 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:

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| Name of Beneficial Owner (1)                                | No. of Shares of Common Stock | Percentage of Class |
|---|-------------------------------|---------------------|
| Harry A. Dugger, III, Ph.D.                                 | 1,829,003 (3)                 | 12.12%              |
| John Klein  | 0 (4)                         | ---                 |
| Donald Deitman  | 0                             | ---                 |
| Robert C. Galler  | 700,000 (5)                   | 4.62%               |
| Robert F. Schaul, Esq.                                      | 264,310 (6)                   | 1.80%               |
| Jack J. Kornreich, Esq.                                     | 244,000 (6)                   | 1.67%               |
| Mohammed Abd El-Shafy                                       | 0 (7)                         | ---                 |
| Lindsay A. Rosenwald  | 13,233,334 (8)                | 62.84%              |
| Biomedical Investment Group, LLC                            | 5,333,334 (8) (9)             | 31.18%              |
| All Executive Officers and Directors as a group (7 persons) | 3,037,599 (3) (4) (5) (6) (7) | 20.21%              |

(1) The address of all holders listed herein is c/o NovaDel Pharma Inc., 31 State Highway 12, Flemington, New Jersey 08822.

(2) Except as otherwise indicated, each named holder has, to our knowledge, sole voting and investment power with respect to the shares indicated. Beneficial ownership as reported in the table above has been determined in accordance with Instruction (4) to Item 403 of Regulation S-B of the Exchange Act.

(3) 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; 108,000 shares owned by his daughter Christina Dugger Sommers; and 108,000 shares owned by his son Andrew Dugger. Dr. Dugger may be deemed to be a "parent" of the Company as such term is defined under the Federal securities laws.

(4) Does not include Non-Plan options, issued in February 2002, to purchase 1,000,000 shares of common stock at an exercise price of \$2.40 per share. These options vest in three equal annual installments, beginning in 2003, and expire in January 2012.

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(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 these options are vested; the remaining 350,000 options are subject to a condition precedent which has not yet been met. The vested options expire in September 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; and 75,000 options issued under the 1998 Option Plan, to purchase common stock at an exercise price of \$2.63 per share, expiring in February 2012.

(7) Does not include Non-Plan options, issued in May 2002, to purchase 150,000 shares of common stock at an exercise price of \$3.02 per share. The options vest equally in November 2002, May 2003 and May 2004 and expire in May 2012.

(8) 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 a limited liability company wholly owned by Lindsay A. Rosenwald

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

The following table sets forth information regarding securities authorized for issuance as of the end of fiscal 2002 with respect to compensation we exchanged for consideration in the form of services.

### 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 | Number of securities remaining available for future issuance |
|--|---|---|--|
|  | (a)   | (b)   | (c)  |
| Equity compensation plans approved by security holders     | 0   | N/A   | N/A  |
| Equity compensation plans not approved by security holders | 3,717,472   | \$1.658   | N/A  |
| <b>TOTAL</b>   | <b>3,717,472</b>  | <b>\$1.658</b>  | <b>N/A</b>   |

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

To the best of management's knowledge, other than 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 fiscal 2002 we paid Mr. Schaul \$125,000 for legal services rendered to us.

In fiscal 1998, we lent the principal amount of \$60,000 to Dr. Dugger in exchange for a 7% promissory note. The note was due on demand, with interest payable quarterly. This note was paid in full in January 2002.

In September 2001, the Company entered into a short-term employment agreement with Robert Galler, who was appointed as Vice President - Corporate Development and a Director. That agreement provided for the issuance to Mr. Galler of options to purchase 700,000 shares of our common stock at an exercise price of \$.75 per share. Under the agreement, the vesting of these options was subject to the satisfaction of certain conditions precedent. In December 2001, the agreement with Mr. Galler was amended to recognize the accomplishment of the conditions. Among other things, the term was extended to three years, his compensation was increased, the options became vested, and he was granted an additional 350,000 options (on the same terms) which would become vested upon satisfaction of a condition in the amended agreement.

During November 2001, we cancelled and reissued certain options under the 1992, 1997 and 1998 Option Plans. An aggregate of 345,000 options were issued to each of Harry A. Dugger and John J. Moroney at an exercise price of \$.70 per share (110% of the market price), having a term of five years. An aggregate of 150,000 options were issued to each of Jack Kornreich and Robert Schaul at an exercise price of \$.63 per share (100% of the market price), having a term of ten years.

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 placement agreement, the company agreed to elect to the Company's Board a Director to be nominated by Dr. Rosenwald (as of this Report, 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 February 2002, we entered into a consulting agreement with John H. Klein, who was simultaneously elected as our chairman of the Board. The agreement is for a term of one year. Under the agreement, Mr. Klein was granted options to purchase 1,000,000 shares of our common stock at an exercise price of \$2.40 per share. The options have a term of ten years and vest in three equal annual installments, beginning in February 2003.

Also in February 2002, 187,500 options were issued under the 1998 Option Plan; 37,500 to John J. Moroney, and 75,000 to each of Jack Kornreich and Robert Schaul. The options have an exercise price of \$2.63 per share and a term of ten years.

Legal Fees

During fiscal 2002 the Company paid Mr. Schaul approximately \$125,000 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:

|   |          |
|---|----------|
| Report of Independent Auditors                | Page F-1 |
| Balance Sheet                                 | F-2      |
| Statements of Operations                      | F-3      |
| Statements of Changes in Stockholders' Equity | F-4      |
| Statements of Cash Flows                      | F-5      |
| Notes to Financial Statements                 | F-6      |

- (a) (2) List of Exhibits

| Incorporated Documents              | SEC Exhibit Reference          |
|-------------------------------------|--------------------------------|
| -----                               | -----                          |
| 2.1 Agreement of Merger dated as of | As filed with the Registrant's |

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|                  |  |  |
|------------------|--|--|
| October 29, 1998 |  | Preliminary Proxy Statement on October 20, 1998,<br>File No. 000-23399               |
| 3.1              | Certificate of Incorporation of the Registrant, as amended               | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 3.2              | Bylaws of the Registrant, as amended                                     | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 4.1              | Form of Warrant Agreement  | As filed with the Registrant's Form SB-2, on October 31, 1997,<br>File No. 333-33201 |
| 4.3              | Form of Class A Warrant Certificate                                      | As filed with the Registrant's Form SB-2, on October 31, 1997,<br>File No. 333-33201 |
| 4.4              | Form of Underwriters' Option Agreement                                   | As filed with the Registrant's Form SB-2, on October 31, 1997,<br>File No. 333-33201 |
| 10.1             | Employment Agreement with Harry A. Dugger, III, Ph.D.                    | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 10.2             | Employment Agreement with John J. Moroney                                | As filed with the Registrant's Form SB-2, on October 3, 1997,<br>File No. 333-33201  |
| 10.3             | Agreement dated December 7, 1996 between the Registrant and Altana, Inc. | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 10.4             | Registrant's 1992 Stock Option Plan                                      | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 10.5             | Form of Option Agreement under the 1992 Stock Option Plan                | As filed with the Registrant's Form SB-2, on October 3, 1997,<br>File No. 333-33201  |
| 10.6             | Registrant's 1997 Stock Option Plan                                      | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 10.7             | Form of Option Agreement under the 1997 Stock Option Plan                | As filed with the Registrant's Form SB-2, on October 3, 1997,<br>File No. 333-33201  |
| 10.8             | Agreement with Rapid Spray (Clemastine) Dated June 2, 1992               | As filed with the Registrant's Form SB-2 Dated August 8, 1997,<br>File No. 333-33201 |
| 10.9             | Agreement with Rapid Spray (Nitroglycerin) dated June 2, 1992            | As filed with the Registrant's Form SB-2, on August 8, 1997,<br>File No. 333-33201   |
| 10.10            | Agreement with Creative Technologies, Inc. dated December 26, 1996       | As filed with the Registrant's Form SB-2, on October 3, 1997,                        |

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File No. 333-33201

|       |                                     |  |
|-------|-------------------------------------|--|
| 10.11 | Registrant's 1998 Stock Option Plan | As filed with the Registrant's Preliminary Proxy Statement on October 20, 1998, File No. 000-23399 |
|-------|-------------------------------------|--|

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|       |   |  |
|-------|---|--|
| 10.12 | Employment Agreement with Donald P. Cox, Ph.D.  | As filed with the Registrant's Form 10-KSB on October 28, 1999, File No. 000-23399     |
| 10.13 | Employment Agreement with Kenneth Cleaver, Ph.D.  | As filed with the Registrant's Form 10-KSB on October 28, 1999, File No. 000-23399     |
| 10.14 | Amendment to Consulting Agreement with Saggi Capital Corp. dated March 25, 1998   | As filed with the Registrant's Form 10-KSB on October 28, 1999 File No. 000-23399      |
| 10.15 | Agreement with Altana, Inc., dated December 7, 1996   | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.16 | Agreement with CLL Pharma dated February 12, 1998   | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 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 Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.18 | Agreement with PolyMASC Pharmaceuticals plc, dated July 25, 2000  | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.19 | Authorization to proceed with Innovex, Inc. and Novartis Pharmaceuticals Corp., dated June 15, 2000   | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.20 | Consulting Agreement with John Klein  | As filed with the Registrant's Form SB-2, on April 15,2002, File No. 333-86262         |
| 10.21 | Employment Agreement with Robert Galler.  | As filed with the Registrant's Form SB-2, on April 15,2002, File No. 333-86262         |
| 10.22 | Employment Agreement Amendment No. 1 with Robert Galler   | As filed with the Registrant's Form SB-2, on April 15,2002, File No. 333-86262         |



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|       |  |   |
|-------|--|---|
| 10.23 | Employment Agreement with Donald Deitman.                            | As filed with the Registrant's Form SB-2, on April 15, 2002, File No. 333-86262   |
| 10.24 | Common Stock and Warrant Purchase Agreement dated December 12, 2001. | As filed with the Registrant's Incorporated by Reference to Schedule 13D filed on December 21, 2001 by Lindsay A. Rosenwald, M.D. |
| 10.25 | Amendment No. 1 to Common Stock and Warrant Purchase Agreement       | As filed with the Registrant's Form SB-2, on April 15, 2002, File No. 333-86262   |
| 10.26 | Employment Agreement with Mohammed Abd El-Shafy, Phd.                | As filed with the Registrant's Form SB-2, Amendment #2, on September 3, 2002, File No. 333-86262                                  |

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- 11.1 \* Computation of earnings per share
- 23.1 \* Consent of Wiss & Company, LLP
- 99.1 \* Certification of Chief Executive Officer and Chief Financial Officer

\* Filed herewith

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the last quarter of fiscal 2002.

### ITEM 14. CONTROLS AND PROCEDURES

Within the 90-day period prior to the date of this report, our Chief Executive Officer and Chief Financial Officer performed an evaluation of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. They concluded that the controls and procedures were effective. Since the date of the evaluation, we have made no significant changes in our internal controls or in other factors that could significantly affect our internal controls.

INDEPENDENT AUDITORS' 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, 2002 and the related statements of operations, changes in stockholders' equity and cash flows 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 misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NOVADEL PHARMA INC. at July 31, 2002, 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, 2002 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 a 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.

WISS & COMPANY, LLP

Livingston, New Jersey  
October 17, 2002

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NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

BALANCE SHEET  
JULY 31, 2002

## ASSETS

### CURRENT ASSETS:

|  |             |             |
|--|-------------|-------------|
| Cash and equivalents.....  | \$3,314,000 |             |
| Accounts receivable - trade, less allowance for doubtful accounts of \$88,000..... | 1,000       |             |
| Prepaid expenses and other current assets.....                                     | 96,000      |             |
|  | -----       |             |
| Total Current Assets.....  |             | \$3,411,000 |

### FURNITURE, FIXTURES, EQUIPMENT

|   |  |         |
|---|--|---------|
| and LEASEHOLD IMPROVEMENTS, LESS ACCUMULATED DEPRECIATION OF \$172,000..... |  | 406,000 |
|---|--|---------|

### OTHER ASSETS

|  |  |             |
|--|--|-------------|
|  |  | 22,000      |
|  |  | -----       |
|  |  | \$3,839,000 |
|  |  | =====       |

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES:

|   |           |            |
|---|-----------|------------|
| Accounts payable-trade.....                         | \$125,000 |            |
| Accrued expenses and other current liabilities..... | 191,000   |            |
|   | -----     |            |
| Total Current Liabilities.....                      |           | \$ 316,000 |

### COMMITMENTS AND CONTINGENCIES

### STOCKHOLDERS' EQUITY :

|   |             |             |
|---|-------------|-------------|
| Preferred stock, \$.01 per value:<br>Authorized 1,000,000 shares, none issued |             |             |
| Common stock \$.001 par value:<br>Authorized - 50,000,000 shares.....         |             |             |
| Issued and outstanding -<br>14,448,817 shares .....                           | 14,000      |             |
| Additional paid-in capital.....   | 13,322,000  |             |
| Accumulated Deficit.....  | (9,813,000) |             |
|   | -----       |             |
| Total Stockholders' Equity .....  |             | 3,523,000   |
|   |             | -----       |
|   |             | \$3,839,000 |
|   |             | =====       |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

STATEMENTS OF OPERATIONS

|  | Year Ended<br>July 31, |                |
|--|------------------------|----------------|
|  | 2002                   | 2001           |
| CONSULTING REVENUES.....                                     | \$ 339,000             | \$ 300,000     |
| CONSULTING EXPENSES.....                                     | 962,000                | 691,000        |
| SELLING, GENERAL AND ADMINISTRATIVE<br>EXPENSES.....         | 3,767,000              | 787,000        |
| LOSS FROM OPERATIONS.....                                    | (4,390,000)            | (1,178,000)    |
| BUY-OUT OF CONSULTANT'S CONTRACT.....                        | (32,000)               | -              |
| INTEREST INCOME.....   | 44,000                 | 23,000         |
| NET LOSS BEFORE TAXES.....                                   | (4,378,000)            | (1,155,000)    |
| DEFERRED INCOME TAX BENEFIT.....                             | 88,000                 | 46,000         |
| NET LOSS.....  | \$ (4,290,000)         | \$ (1,109,000) |
|  | =====                  | =====          |
| BASIC AND DILUTED LOSS<br>PER COMMON SHARE:                  |                        |                |
| Net Loss.....  | \$ (.38)               | \$ (.18)       |
|  | =====                  | =====          |
| WEIGHTED AVERAGE NUMBER OF COMMON<br>SHARES OUTSTANDING..... | 11,361,000             | 6,326,000      |
|  | =====                  | =====          |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

Common Stock

-----  
Additional

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|   | Shares     | Par Value | Paid-in Capital | Accumulated Deficit | Stockholders' Equity |
|---|------------|-----------|-----------------|---------------------|----------------------|
| -----   |            |           |                 |                     |                      |
| BALANCE,<br>JULY 31, 2000   | 5,877,300  | \$ 6,000  | \$ 5,250,000    | \$ (4,414,000)      | \$ 842,000           |
| -----   |            |           |                 |                     |                      |
| YEAR ENDED  |            |           |                 |                     |                      |
| JULY 31, 2001   |            |           |                 |                     |                      |
| Common Shares<br>Issued for<br>Services   | 3,937      | -         | 6,000           | -                   | 6,000                |
| In connection<br>with private<br>placement,<br>net of costs                             | 1,843,663  | 2,000     | 1,155,000       | -                   | 1,157,000            |
| Net Loss  | -          | -         | -               | (1,109,000)         | (1,109,000)          |
| -----   |            |           |                 |                     |                      |
| BALANCE,<br>JULY 31, 2001   | 7,724,900  | \$ 8,000  | \$ 6,411,000    | \$ (5,523,000)      | \$ 896,000           |
| -----   |            |           |                 |                     |                      |
| YEAR ENDED  |            |           |                 |                     |                      |
| JULY 31, 2002   |            |           |                 |                     |                      |
| Common Shares<br>Issued in<br>connection with<br>private<br>placements,<br>net of costs | 6,666,667  | 6,000     | 4,910,000       | -                   | 4,916,000            |
| Shares issued<br>for Options<br>exercised   | 7,765      | -         | -               | -                   | -                    |
| Shares issued<br>for Warrants<br>exercised  | 49,485     | -         | -               | -                   | -                    |
| Options issued<br>for services  | -          | -         | 1,947,000       | -                   | 1,947,000            |
| Warrants issued<br>for services   | -          | -         | 54,000          | -                   | 54,000               |
| Net Loss  | -          | -         | -               | (4,290,000)         | (4,290,000)          |
| -----   |            |           |                 |                     |                      |
| BALANCE,<br>JULY 31, 2002   | 14,448,817 | \$14,000  | \$13,322,000    | \$ (9,813,000)      | \$ 3,523,000         |
| =====   |            |           |                 |                     |                      |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC  
(Formerly Flemington Pharmaceutical Corporation)

STATEMENTS OF CASH FLOWS

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|   | Year Ended<br>July 31, |                |
|---|------------------------|----------------|
|   | 2002                   | 2001           |
| CASH FLOW FROM OPERATING ACTIVITIES:  |                        |                |
| Net loss  | \$ (4,290,000)         | \$ (1,109,000) |
| Adjustments to reconcile net loss to<br>net cash flows from operating activities: |                        |                |
| Shares issued for services  | -                      | 6,000          |
| Options issued for services   | 1,947,000              | -              |
| Warrants issued for services  | 54,000                 | -              |
| Depreciation and amortization   | 77,000                 | 24,000         |
| Allowances for Doubtful Accounts  | 79,000                 | -              |
| Changes in operating assets and liabilities:                                      |                        |                |
| Accounts receivable   | 12,000                 | (46,000)       |
| Due from D&O Insurance Carrier  | -                      | 86,000         |
| Demand note receivable, Officer   | 60,000                 | -              |
| Prepaid expenses and other current assets   | (39,000)               | (5,000)        |
| Due from Joint Venture partner for<br>reimbursable expenses                       | 6,000                  | 74,000         |
| Other Assets  | (5,000)                | (7,000)        |
| Accounts payable - trade  | 114,000                | (57,000)       |
| Billings in excess of costs and estimated<br>earnings on uncompleted contracts    | -                      | (49,000)       |
| Accrued expenses and other current liabilities                                    | 114,000                | (23,000)       |
| Net cash flows from operating activities  | (1,871,000)            | (1,106,000)    |
| CASH FLOWS FROM INVESTING ACTIVITIES -  |                        |                |
| Purchase of property and equipment  | (316,000)              | (166,000)      |
| Net cash flows from investing activities  | (316,000)              | (166,000)      |
| CASH FLOWS FROM FINANCING ACTIVITIES -  |                        |                |
| Proceeds received from private placements   | 4,916,000              | 1,157,000      |
| Net cash flows from financing activities  | 4,916,000              | 1,157,000      |
| NET CHANGE IN CASH  | 2,729,000              | (115,000)      |
| CASH, BEGINNING OF YEAR   | 585,000                | 700,000        |
| CASH, END OF YEAR   | \$3,314,000            | \$ 585,000     |
| SUPPLEMENTAL CASH FLOW INFORMATION:   |                        |                |
| Interest paid   | \$ -                   | \$ -           |
| Income taxes paid   | \$ -                   | \$ -           |

See accompanying notes to financial statements.

NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

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 domestic and international consulting activities and the development of novel pharmaceutical products combining presently marketed drugs with innovative 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. Management intends to develop the products in collaboration with pharmaceutical companies having significant existing sales of the pharmaceutical compounds being incorporated into the Company's dosage delivery systems, thereby creating a more effective and more attractive product.

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

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, amounts due from joint venture partner and insurance carrier, loans to stockholders, accounts payable, and accrued expenses. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values, based on market information available to management.

Furniture, Fixtures and Equipment - Furniture, fixtures and equipment 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 and equipment.

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.

Defined Contribution Retirement Plans - The Company has a Simple IRA retirement plan providing for contributions at management's discretion. During the years ended July 2002 and July 2001, the Company made contributions to the retirement plan of approximately \$11,000 and approximately \$15,000, respectively.

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### 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, at times, may exceed the FDIC limits.
- (b) Major Customers - During fiscal 2002, the Company had revenue from two customers located in the USA approximating 46% and 40%, respectively, of the Company's total revenue.

During fiscal 2001, the Company had revenue from two customers located in the United States approximating 40 % and 18 %, respectively, of the Company's total revenue.

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- (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.

Recent Accounting Pronouncements - In August 2001, the FASB issued, SFAS No. 143, Accounting for Asset Retirement Obligations, which requires companies to record a liability at fair value for asset retirement obligations in the period in which they are incurred. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. This Statement is effective for the Company for the fiscal year beginning June 1, 2003. The Company is currently evaluating the provisions of this Statement, but does not believe adoption of the statement will result in material impact to its results of operations or financial position. In October 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which provides a single accounting model for long-



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lived assets to be disposed of. This Statement is effective for the Company for the fiscal year beginning August 1, 2002. The Company is currently evaluating the provisions of this Statement, but does not anticipate that adoption will result in a material impact to its results of operations or financial position.

### 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 - Prepaid and Accrued expenses:

Accrued expenses and other current liabilities - Approximately \$77,000 of accrued vacation salary and related payroll taxes due to the Company's employees, approximately \$27,000 of study costs, approximately \$48,000 of legal fees and approximately \$20,000 of accrued salary and related payroll taxes due to the Company's employees are included in the \$191,000 total. The remainder is accrued expenses and other current liabilities.

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### Note 4 - Furniture, Fixtures and Equipment

Furniture, fixtures and equipment is summarized as follows:

|                               | July 31, 2002 |
|-------------------------------|---------------|
| Equipment                     | \$ 510,000    |
| Furniture and fixtures        | 40,000        |
| Leasehold improvements        | 28,000        |
|                               | -----         |
|                               | 578,000       |
| Less:Accumulated depreciation | 172,000       |
|                               | -----         |
|                               | \$ 406,000    |
|                               | =====         |

### Note 5 - Stockholders' equity:

Preferred Stock - The Company's Certificate of Incorporation

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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:

Legal Fees - The Company has incurred legal fees with an officer and director of the Company. These fees approximated \$125,000 and \$85,000 for the years ended July 31, 2002 and 2001, respectively.

Stockholder's Note Receivable - In April 1998, the Company lent \$60,000 to its President. The note was paid in full, together with all accrued interest, in January 2002.

Consulting Agreement - In February 2002 the Company entered into a consulting agreement with John H. Klein, effective February 1, 2002 (see Note 7 (d) ). In addition, in February 2002, Mr. Klein was elected as a member and Chairman of the Company's Board of Directors.

### Note 7 - Commitments and Contingencies:

(a) During January 2002, the Company entered into a consulting agreement, and will pay \$25,000 per quarter through December 31, 2002 for investor relations with the Trout Group, LLC.

(b) The Company entered into an employment agreement with its President for a base 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.

(c) 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.

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(d) The Company entered into an employment agreement with its Vice President Corporate Development for a base annual salary of \$120,000, 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 700,000 of such options

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had vested.

(e) 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 Chairman 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.

(f) 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.

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 \$75,000 and \$69,000 for the years ended July 31, 2002, and 2001 respectively.

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, 2002 and 2001.

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

|  | July 31   |             |
|--|-----------|-------------|
|  | 2002      | 2001        |
| Differences between the cash basis of accounting for income tax reporting and the accrual basis for financial reporting purposes | \$ -      | \$ (27,000) |
| Net operating loss carryforwards.....  | 2,890,000 | 2,003,000   |
|  | 2,890,000 | 1,976,000   |
| Valuation allowance  | 2,890,000 | 1,976,000   |

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|                             |       |       |
|-----------------------------|-------|-------|
| Net deferred tax asset..... | ----- | ----- |
|                             | \$ -  | \$ -  |
|                             | ===== | ===== |

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

|   | 2002        | 2001       |
|---|-------------|------------|
|   | -----       | -----      |
| Federal Tax at statutory rate.....                  | \$1,459,000 | \$ 377,000 |
| State Income Tax.....                               | 257,000     | 48,000     |
| Non deductible; options issued for<br>services..... | (802,000)   | -          |
| Valuation allowance.....                            | (914,000)   | (425,000)  |
|   | -----       | -----      |
|   | \$ -        | \$ -       |
|   | =====       | =====      |

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax asset 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, 2002 and 2001.

At July 31, 2002, the Company has federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately \$7,900,000 and \$5,500,000, respectively, which can be used to offset current and future taxable income through the year 2023.

Note 9 - Stock Options:

At July 31, 2002, 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 1,075,000 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 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 \$1,440,000 or \$.13 per share to \$5,730,000 or \$.51 per share for fiscal 2002. There were no options granted in fiscal 2001.

The fair value of options granted in fiscal 2002 were estimated at the date of grant using a Black-Sholes option model with the following weighted-average assumptions, respectively: risk-free interest rates of 5.7%

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yield of 0.0% volatility factors of the expected market price of the Company's Common Stock of 99% and a weighted-average expected life of the options of five (5) to ten (10) 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 input of highly subjective assumptions including the expected stock price volatility. When the Company shares were not traded publicly, the employee stock options had characteristics significantly different from those of publicly traded options. Because changes in the subjective input assumptions can materially affect fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single estimate of the fair value of its employee stock options.

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

|                                | Options<br>Available<br>for Grant | -----<br>Number of Options<br>Options<br>----- | -----<br>Exercise<br>Price<br>----- |
|--------------------------------|-----------------------------------|--|-------------------------------------|
| Balance at August 1, 2000....  | -                                 | 2,300  | \$1.53                              |
| Grants.....                    | -                                 | -  | -                                   |
| Exercises.....                 | -                                 | -  | -                                   |
| Cancellations.....             | -                                 | -  | -                                   |
| Balance at July 31, 2001.....  | -----<br>-                        | -----<br>2,300                                 | -----<br>\$1.53                     |
| Additional Shares reserved.... | 2,475                             | -  | -                                   |
| Grants.....                    | 3,378                             | 3,378  | 1.60                                |
| Exercises.....                 | 10                                | 10   | .63                                 |
| Cancellations.....             | 1,190                             | 1,190  | 1.42                                |
| Balance at July 31, 2002.....  | -----<br>277<br>=====             | -----<br>4,478<br>=====                        | -----<br>\$1.61<br>=====            |

Option price per share: \$.63 - \$3.18  
Options exercisable: 3,328,000

The following table summarizes significant ranges of outstanding and exercisable options at July 31, 2002 (in thousands, except exercise price amounts):

| Outstanding Options<br>----- | Options Exercisable<br>----- |
|------------------------------|------------------------------|
|------------------------------|------------------------------|

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| Range of Exercise Prices | Options | Weighted Average Remaining Life in Years | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
|--------------------------|---------|--|---------------------------------|---------|---------------------------------|
| \$0.01 - \$1.00.....     | 2,030   | 6.7                                      | \$ .74                          | 2,030   | \$ .74                          |
| \$1.01 - \$2.00.....     | 860     | 4.1                                      | 1.84                            | 860     | 1.84                            |
| \$2.01 - \$3.00.....     | 1,188   | 9.5                                      | 2.44                            | 188     | 2.63                            |
| \$3.01 - \$4.00.....     | 400     | 9.7                                      | 3.12                            | 250     | 3.18                            |
|                          | 4,478   | 7.2                                      | \$ 1.61                         | 3,328   | \$ 1.38                         |

In addition to stock options issued by the Company under the Plans, the Company has reserved 11,364,781 shares of common stock for non-plan options and warrants as detailed below.

Non-plan Options and Warrants - At July 31, 2002 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 2002, to purchase a like number of shares of Common Stock at an exercise price of \$5.80 per share.

B. 68,000 warrants, issued to the Underwriter in connection with the Public Offering, exercisable until November 2002, to purchase 68,000 units, each consisting of one share of Common Stock and one Class A Warrant at an exercise price of \$9.74 per unit. Each Class A Warrant included in the units is exercisable on the same terms as is described above in paragraph A.

C. 2,700,000 stock options, not issued under any of the plans, as follows:

\* 300,000 options each issued on November 19, 1997, vesting immediately, to the Company's President and former Chairman of the Board of Directors, for a total of 600,000, having an exercise price of \$1.84 per share, issued in connection with their respective employment agreements in June 1997, exercisable until November 2007.

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\* 700,000 options issued in December 2001, vesting immediately, to the Company's Vice President for Corporate Development, in connection with his employment agreement, exercisable until December 2011. There is a contingency in that employment agreement which, if satisfied, would result in the issuance of an additional 350,000 options; the Company has reserved shares to meet that contingency.

\* 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,

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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.

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

E. 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.

F. 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.

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

H. 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.

I. 240,114 warrants at \$.75 per share issued to broker/dealers in connection with the fiscal year 2001 private placement. 50,000 of such warrants expire in October 2010, and remaining warrants (190,114 shares) expire in May 2011.

### Note 10 - Subsequent Events:

In October 2002 the Company 75,000 options under the 1998 option plan and 200,000 Non-Options Plan to its President. These options vest immediately, have an exercise price of \$1.30 and expire during October 2007.

In November, 2002, the Company decided to extend for one year the expiration date of its publicly traded warrants (i.e. to November 18, 2003). All other provisions of the warrants remain unchanged.

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### 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.

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By: /s/ Harry A. Dugger III

-----  
Harry A. Dugger, III, President

Date: October

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/ Harry A. Dugger, III<br>-----<br>Harry A. Dugger, III                            | President and Chief Executive Officer (Principal and Executive Officer) and Director | Nov. 12, 2002 |
| /s/ Donald J. Deitman<br>-----<br>Donald J. Deitman<br>(Principal Financial Officer) | Chief Financial Officer (Principal Financial Officer)                                | Nov. 12, 2002 |
| /s/ John H. Klein<br>-----<br>John H. Klein  | Chairman of the Board and Director   | Nov. 12, 2002 |
| /s/ Robert F. Schaul<br>-----<br>Robert F. Schaul                                    | Secretary and Director   | Nov. 12, 2002 |
| /s/ Jack J. Kornreich<br>-----<br>Jack J. Kornreich<br>October                       | Director   | Nov. 12, 2002 |
| /s/ Robert C. Galler<br>-----<br>Robert C. Galler                                    | Director   | Nov. 12, 2002 |

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CERTIFICATION

I, Harry A. Dugger III, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-KSB of NovaDel Pharma Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material



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respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors and material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

Harry A. Dugger III, Ph.D  
President & CEO

/s/ Harry A. Dugger III

-----

(Signature)

CERTIFICATION

I, Donald J. Deitman, certify that:

1. I have reviewed this annual report on Form 10-KSB of NovaDel Pharma Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to

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make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors and material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

Donald J. Deitman  
Chief Financial Officer

/s/ Donald J. Deitman  
-----  
(Signature)

\* \* \* \* \*

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EXHIBIT 11

NOVADEL PHARMA INC.  
(Formerly Flemington Pharmaceutical Corporation)

EARNINGS PER SHARE COMPUTATION

|  | YEAR ENDED<br>JULY 31, 2002 |
|--|-----------------------------|
|  | -----                       |
|  | BASIC                       |
|  | -----                       |
| Weighted average shares outstanding            | 11,361,000                  |
| Dilutive effect of stock performance plans (1) | --                          |
|  | -----                       |
| Total  | 11,361,000                  |
| Net Income (loss)                              | (4,290,000)                 |
|  | -----                       |
| Earnings per share                             | (.38)                       |
|  | -----                       |
|  | YEAR ENDED<br>JULY 31, 2001 |
|  | -----                       |
|  | BASIC                       |
|  | -----                       |
| Weighted average shares outstanding            | 6,326,000                   |
| Dilutive effect of stock performance plans (1) | --                          |
|  | -----                       |
| Total  | 6,326,000                   |
| Net Income (loss)                              | (1,109,000)                 |
|  | -----                       |
| Earnings per share                             | (.18)                       |
|  | -----                       |

(1) Since the company has reported a loss for each period, no potential shares from stock performance plans have been presented, as their effect would be anti-dilutive.

\* \* \* \* \*

Exhibit 23

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (Registration Number 333-42103) of our report dated October 17, 2002, on the financial statements for the two years in the period ended July 31, 2002, which appear in the Form 10-KSB.

Wiss & Company, LLP

Livingston, New Jersey  
October 17, 2002

\* \* \* \* \*

Exhibit 99.1

CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NovaDel Pharma Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-KSB for the year 2002 ended July 31, 2002 of the Company fully complies with the requirements of section 13 (a) or

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15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-KSB fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2002

/s/ Harry A. Dugger III  
-----  
Harry A. Dugger III, Ph.D  
President & Chief Executive  
Officer

Dated: November 12, 2002

/s/ Donald J. Deitman  
-----  
Donald J. Deitman  
Chief Financial Officer